ILLINOIS EMERGENCY MANAGEMENT AGENCY
DIVISION OF NUCLEAR SAFETY

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September 2005

Instructions for Preparing Applications
for Radioactive Material Licenses Authorizing the

MEDICAL USE OF RADIOACTIVE MATERIAL

BUREAU OF RADIATION SAFETY
Radioactive Materials Section
1035 Outer Park Drive
Springfield, Illinois 62704
(217) 785-9947

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I. INTRODUCTION

A. General

The ILLINOIS EMERGENCY MANAGEMENT AGENCY (herein referred to as IEMA or the Agency) regulates the possession of radioactive material and the intentional internal or external administration of radioactive material, or the radiation therefrom, to human beings. This type of use is called medical use, and a specific license issued pursuant to 32 Illinois Administrative Code 330.260(a) & (b) (the IEMA administrative rules, herein referred to as 32 Ill. Adm. Code or the regulations) is required.

The Agency usually issues a single radioactive material license to cover an entire radioactive material program. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the medical facility. Facilities with more than one license may wish to combine those licenses where feasible.

B. Purpose of Instructions

These instructions describe the information needed by the Agency's Radioactive Materials Section staff to evaluate an application for a specific license for the possession and medical use of radioactive material. These instructions do not contain guidance for specific licenses for academic medical programs on campuses that do not include hospitals or clinics where radioactive material is used in or on humans, broad scope programs or the use of radioactive material in remote afterloaders or teletherapy units. If the applicant is preparing an application for a broad scope program or the use of a remote afterloader or teletherapy unit, the Agency must be contacted for additional guidance documents that specify the information that must be provided. Guidance for use of emergency medical technologists are addressed under separate guidance documents that can be obtained by contacting the Agency.

Prior to submitting an application for medical use, the applicant should carefully study these instructions and the regulations listed in Section I.(D.), and submit all applicable information requested. The Radioactive Materials Section staff will request additional information when necessary to ensure that the applicant has established an adequate radiation safety program (32 Ill. Adm. Code 330.240 and 230.250. Such requests for additional information will delay final action regarding the application and may be avoided by a thorough study of the regulations and these instructions prior to filing the application.

These instructions are intended only for general guidance in the preparation of the license application and should not be considered as a substitute for the applicant's careful evaluation of the proposed use of radioactive material. Applicants must assure that the application correctly and adequately describes radiation safeguards and procedures to be followed in their radioactive material use program.

C. Purpose of Appendices to these Instructions

The regulations require licensees to develop and implement written policies and procedures that ensure compliance with the regulations. The appendices to this instructional set provide sample radiation safety procedures that the licensee may choose to use in their radiation safety program. Applicants should carefully read the applicable regulations and sample procedures and then decide if the sample procedures are appropriate for their specific radiation safety needs. In the application, applicants may certify that they will follow a sample procedure or they may develop and submit an equivalent procedure for Agency review. If a sample procedure is followed, applicants must ensure that references to that procedure are clear and specific (e.g., references should include instructional set number, revision number, revision date and appendix identification).

D. Applicable Regulations

The following portions of the regulations are applicable to the medical use of radioactive material and should be used in conjunction with these instructions:

1. 32 Ill. Adm. Code 310 - "General Provisions"
2. 32 Ill. Adm. Code 326 - “Financial Assurance Requirements”
3. 32 Ill. Adm. Code 330 - "Licensing of Radioactive Material"
4. 32 Ill. Adm. Code 331 - "Fees for Radioactive Material Licenses"
5. 32 Ill. Adm. Code 335 - "Use of Radionuclides in the Healing Arts"
6. 32 Ill. Adm. Code 340 - "Standards for Protection Against Radiation"
7. 32 Ill. Adm. Code 400 - "Notices, Instructions and Reports to Workers; Inspections"
8. 32 Ill. Adm. Code 401 - "Accrediting Persons in the Practice of Medical Radiation Technology."

The Agency may amend the regulations periodically to remain compatible with current standards. The licensee will be notified of the changes as they occur and must incorporate them into their program, if applicable.

E. Radiation Protection Program

As specified in 32 Ill. Adm. Code 340.110, the licensee must develop, document and implement a radiation protection program. Specifically, this program should include provisions for ensuring compliance with the requirements of Part 340 of the regulations, the license, the license conditions with all active amendments, for establishing an ALARA program, and for performing reviews of the program at 12-month intervals. In developing a radiation protection program, the licensee should design the program based on the size of

the facility, potential hazards associated with radiation exposure, the potential for intake of radioactive material and the physical characteristics of the radionuclides. The commitments made to the Agency, which lead to the issuance of the license, the regulations and the complete license document, are considered the applicant's radiation protection program.

Active control over the radiation protection program should be exercised by management personnel in positions of authority. In addition, management should be aware that the assignment of duties to individuals (e.g., the Radiation Safety Officer) does not relieve management of the responsibilities to review and control the licensed activities.

F. Retention of Records

The licensee must maintain certain records for specified periods of time for compliance purposes. These intervals have been established in order for the inspection staff and other authorized entities to have access to these documents as required by the 32 Ill. Adm. Code. Appendix A of this instructional set contains the retention requirements for these records.

G. As Low As Is Reasonably Achievable (ALARA)

Persons engaged in activities authorized by radioactive material licenses issued by the Agency must, to the extent practicable, make every reasonable effort to maintain the release of radioactive material and the total effective dose equivalent (TEDE) ALARA, for both workers and members of the public. License applicants must give consideration to the ALARA philosophy when designing facilities, procuring equipment and developing procedures for work with radioactive material. The ALARA concept is a key element in establishing any radiation protection program as described above. The definition of ALARA may be found in 32 Ill. Adm. Code 310.20.

Each medical licensee must have a formal written radiation protection program that incorporates the ALARA philosophy in accordance with 32 Ill. Adm. Code 335.1010(a). The success of an ALARA program depends on the cooperation of each individual working at the licensee's facility. The licensee's management must retain a current written description of the radiation protection program that includes a formal commitment to the ALARA philosophy in accordance with 32 Ill. Adm. Code 335.1010(b)(1). In addition, 32 Ill. Adm. Code 335.1010 requires that medical institutions have a Radiation Safety Committee to review such uses regarding safety and ALARA considerations.

H. Système International (SI) Units

In accordance with State and federal policy, the Agency is making an effort to implement the SI system of units. If applicants wish to utilize SI units in their application, please feel free to do so. However, this conversion is by no means mandatory at this time. The Agency will continue to recognize SI and English units. Appendix B of this instructional set has been included to assist applicants in the use of SI units.

II. FILING AN APPLICATION

An application for a specific license for the medical use of radioactive material should be submitted on form IL 473-00272, "Application Form for a Medical Radioactive Material License," in accordance with 32 Ill. Adm. Code 330.240(a) (see Exhibit A). Section V contains information for filing renewals. All items on the application form must be completed in sufficient detail for the Agency staff to determine that the applicant's equipment, facilities and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on form IEMA.FLM-001M is limited, separate 8.5 by 11 inch sheets of paper may be appended for Items 5.a. through 23 listed on the form. Each appended sheet should contain the item number, page number, applicant's name and the application date in the lower right corner.

The application must be completed in triplicate. The original and one copy of the application, along with duplicate copies of supporting documents, must be mailed to:

Illinois Emergency Management Agency
Division of Nuclear Safety
Radioactive Materials Section
1035 Outer Park Drive
Springfield, Illinois 62704

At least one copy of the submitted application, with all attachments, must be retained by the applicant. When issued, the license will require, as a condition, that the licensee possess and use radioactive material described in all schedules of the license in accordance with statements, representations and procedures contained in or enclosed with, the application and supporting documentation. The regulations contained in 32 Ill. Adm. Code: Chapter II, Subchapters b and d shall govern unless the statements, representations and procedures set forth in the licensee's application and correspondence or the radioactive material license are more restrictive than the regulations.

Unless the applicant is exempt, an application fee is required for a radioactive material license. Refer to 32 Ill. Adm. Code 331 to determine the appropriate fee. The regulations also include a requirement for payment of an annual recovery/remediation fee for use in cases where such costs for decontamination/disposal cannot be recovered from the responsible parties or available surety documents. You will receive a billing statement from the Agency in accordance with the annual and recovery/remediation fees noted in 32 Ill. Adm. Code 331, Appendix F. Please submit your fee payments after you have received this statement from the Agency. **Please do not submit your fee payments or recovery/remediaton fees with your renewal.** Also, please note that 32 Ill. Adm. Code 330.320(c) requires licensees to submit either a renewal application or a termination request no less than 30 days before the expiration date of an existing license.

III. CONTENTS OF APPLICATION

The following paragraphs explain the information requested on Form IL 473-00272 "Application Form for a Medical Radioactive Material License" (Exhibit A):

Item 1 - Type of Application

Indicate, by checking the appropriate box, if the application is for a new license, an amendment to an existing license or a renewal of an existing license. If the application is for an amendment to or a renewal of an existing license, please specify the existing Illinois Radioactive Material License number in the space provided.

Item 2 - Applicant's Name and Mailing Address

The "applicant" is the organization or person(s) legally responsible for possession and use of the licensed radioactive material specified in the application. The applicant's mailing address may or may not be the same as the address where radioactive material will be used. If the request is for a license for a private practice, enter the name of the physician or partnership. An individual should be designated as the applicant only if that individual is acting in a private capacity and the use of radioactive material is not connected with his or her employment with a corporation or other legal entity. Enter the name, mailing address (including ZIP code), telephone number (including area code), fax and email address of the applicant in the space provided.

Item 3 - Person to Contact Regarding This Application

The applicant should name a qualified individual who is authorized by the applicant's management to answer questions and make commitments regarding the application and the radiation safety program. This individual, usually the Radiation Safety Officer (RSO) or a principal radioactive material user, will serve as the point of contact during the application's review. In the space provided, enter the name, address and telephone number (including area code), fax and email address of the individual to be contacted regarding the application.

Item 4 - Address(es) Where Radioactive Material Will Be Used and/or Stored

Specify all the addresses and physical locations where licensed material will be used and/or stored. Each location description should include the street address, city and other descriptive information (e.g., building name/number, suite, room or floor number) to allow easy facility identification. If multiple addresses will be used, then specify the extent of use at each location. Additionally, if more than one permanent facility is used, specify where records will be maintained for each facility. Do not specify a post office box number as a use location. If the applicant does not own the use/storage location(s), verification that the owner is aware of the use/storage of radioactive material on this property must be submitted.

Use of temporary job sites should be requested by checking the blank box provided under Item 4 on the application. Use of licensed material at temporary job sites will become part of the license conditions and each separate address does not need to be specified so long as the licensee does not use or store radioactive material at any one site for more than 180 days during any twelve-month period.

Item 5a - Individuals Who Will Use Radioactive Material

List the full names of all persons who will use or directly supervise use of radioactive material and specify the categories of radioactive material for which you wish each person to be authorized. Categories of use are found in 32 Ill. Adm. Code 335 Subparts D, E, F, G, H and I.

Physicians who will use or directly supervise the human use of radioactive material must be licensed to practice medicine in accordance with the laws of Illinois and must have clinical radionuclide training and experience commensurate with the proposed radioactive material use. Additional responsibilities of authorized users are contained in 32 Ill. Adm. Code 335.1060. Criteria for evaluating physician training and experience, in order to authorize medical use of radioactive material, is specified in 32 Ill. Adm. Code 335 Subpart J. A physician specifically listed as an authorized user on an existing radioactive material license may submit a copy of that license (or reference an Illinois radioactive material license number) as evidence of training and experience.

If a physician is certified by an organization listed in 32 Ill. Adm. Code 335 Subpart J, then submit a completed Supplement A (see Exhibit B). A physician certified as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FFRC) who desires to perform radiation therapy should submit a copy of the certificate and evidence of specialization in radiation therapy. Physicians not previously authorized by the Agency, the U.S. Nuclear Regulatory Commission (NRC), an Agreement State, or a Licensing State and not certified by another appropriate organization must submit a complete description of their training and experience using Supplement A (see Exhibit B). Each physician's training and experience will be reviewed on a case-by-case basis; and, when appropriate, the Agency will request the assistance of its Medical Use Advisory Board.

Item 5b - Teletherapy Physicist

Teletherapy Physicists who will use or directly supervise the use of radioactive material for uses identified in 32 Ill. Adm. Code 335 Subpart I, must meet the training and experience requirements identified in 32 Ill. Adm. Code 335.9150. A teletherapy physicist specifically listed on an existing radioactive material license may submit a copy of that license (or reference an Illinois Radioactive Material License number) as evidence of training and experience or may submit a complete description of their training and experience using Supplement A (see Exhibit B).

Item 6 - Radiation Safety Officer (RSO)

State the name and job title of the RSO. This person is designated by, and responsible to, the applicant's management for the coordination of the applicant's radiation safety program and for ensuring compliance with the applicable regulations and license provisions. If the RSO is not a proposed authorized user, then submit a complete description of that individual's training and experience relative to the handling of radioactive material requested in the application. The RSO must meet the minimum training and experience requirements of 32 Ill. Adm. Code 335.9010 or 335.9020. The

minimum duties and responsibilities of the RSO are specified in 32 Ill. Adm. Code 335.1020(b).

In order to comply with 32 Ill. Adm. Code 335.1020(a), the RSO should be a full-time employee of the applicant. Even if the applicant employs a consultant to assist the RSO, the licensee is still responsible for assuring the radiation safety program is run in accordance with the application and the regulations.

Item 7a - Radioactive Material for Medical Use

32 Ill. Adm. Code 335 is divided into six categories of use. For routine medical use, the applicant should indicate on forms IL 473-00272 or IL 473-0337, the type and quantity of radioactive material requested for each category of use. The following describes the types of radioactive material uses authorized by the different sections in 32 Ill. Adm. Code 335, and indicates information that needs to be submitted to obtain approval for the use of that material.

A. 32 Ill. Adm. Code 335.3010 (Subpart D)

This section refers to the diagnostic use of radiopharmaceuticals involving measurements of uptake, dilution and excretion. Radiopharmaceuticals authorized for use under this section are those for which the Food and Drug Administration (FDA) has granted approval.

B. 32 Ill. Adm. Code 335.4010 (Subpart E)

This section refers to the use of radiopharmaceuticals, generators and reagent kits for imaging and localization studies. Radiopharmaceuticals, generators or reagent kits used for the preparation and diagnostic use of radiopharmaceuticals authorized for use under this section are those for which the FDA has granted approval.

Applicants planning to use Positron Emission Tomography (PET) radionuclides for imaging must include information detailing special safety precautions to be taken when handling high-energy, short-lived radionuclides. Applicants must indicate whether or not they intend to acquire radiopharmaceuticals prepared and distributed in accordance with a specific license. If they intend to acquire radionuclides distributed in accordance with a specific license and perform the pharmaceutical labeling at the licensee's facility, then the labeling and radiopharmaceutical testing procedures must be submitted to the Agency. In addition, licensees wishing to install a self-shielded cyclotron for production of radionuclides should contact the Agency regarding information to be submitted.

NOTE: The Agency will not authorize the use of radioactive gas/volatile material in this subsection unless the applicant also submits the information required in Item 22 of the application.

C. 32 Ill. Adm. Code 335.5010 (Subpart F)

This section refers to the therapeutic use of radiopharmaceuticals for which the FDA has accepted an "Investigational New Drug Application" (IND) or approved a "New Drug Application" (NDA).

D. 32 Ill. Adm. Code 335.6010 (Subpart G)

This section refers to the use of iodine-125 (I-125), americium-241 (Am-241) and gadolinium-153 (Gd-153) as sealed sources for use in either bone mineral analyzers or diagnostic imaging devices. The use of such sources must be in accordance with the manufacturer's radiation safety and handling instructions. In addition, sealed sources used in devices, as authorized by this section, must be sources that have been evaluated for use in the specific device they will be used. Such evaluations must be listed in a Agency-accepted publication such as the U.S. NRC's "Registry of Radioactive Sealed Sources and Devices" (SS&D) or the U.S. Department of Health and Human Services' "Radioactive Material Reference Manual" (RMRM).

E. 32 Ill. Adm. Code 335.7010 (Subpart H)

This section refers to the use of sealed sources for brachytherapy. Such sources must be used in accordance with the manufacturer's radiation safety and handling instructions and the sealed sources must be evaluated for use and listed in a Agency-accepted publication such as the U.S. NRC's "Registry of Radioactive Sealed Sources and Devices" (SS&D) or the U.S. Department of Health and Human Services' "Radioactive Material Reference Manual" (RMRM).

In addition, the use of sealed sources listed in 32 Ill. Adm. Code 335.7010 in remote afterloading brachytherapy devices must be specifically addressed in licensing correspondence and their use approved by the Agency in the license document prior to the licensee's use of sealed sources in these types of devices. The applicant should request additional guidance from the Agency regarding the use of remote afterloaders.

F. 32 Ill. Adm. Code 335.8010 (Subpart I)

This section refers to the therapeutic use of cobalt-60 (Co-60) or cesium-137 (Cs-137) as a sealed source (or several sealed sources for use in a stereotactic treatment device) in a teletherapy unit. If you wish authorization to use a teletherapy unit to irradiate materials other than humans, such as blood and blood products, you must indicate that in your license application.

Item 7b - Radioactive Material for Uses Not Listed in Item 7a

For uses not listed in Item 7.a. and for possession of materials for non-human use, list, for each radionuclide to be used, the chemical and physical form, the maximum activity

you wish to possess at any one time and the intended use of the material. This would include authorization for *in vitro* material in amounts greater than allowed by 32 Ill. Adm. Code 330.220(f), depleted uranium for linear accelerator shielding, instrument calibration sources, etc. In addition, if you wish to be licensed to possess and use sealed sources, specify the manufacturer's name, nuclide, source model, the maximum activity per source and the total number of sources you wish to possess.

Item 8 - Radiation Safety Committee

In accordance with 32 Ill. Adm. Code 335.1030, each medical institution applying for a radioactive material license for human use is required to establish a Radiation Safety Committee (RSC) comprised of at least three members. Although most medical clinics and private practices do not meet the definition of a medical institution, such facilities that authorize the possession and/or use or radioactive material authorized under 32 Ill. Adm. Code 335.5010, 335.7010 or 335.8010 are considered medical institutions and are required to establish a RSC.

The RSC evaluates all proposals for the use of radionuclides. In accordance with 32 Ill. Adm. Code 335.1030(a)(1), Committee membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service and a representative of management who is neither an authorized user nor the RSO. The management representative must be someone who has the authority to obligate the institution's resources, including the commitment of financial resources, if necessary. A representative from nursing is not necessary if the facility is only using diagnostic radionuclides. Other members of the RSC should attend at least two meetings each year.

The RSC's minimum responsibilities and duties relative to radioactive material are described in 32 Ill. Adm. Code 335.1030(b). The applicant should submit any additional responsibilities or duties of the RSC that are not contained in the regulations and are specific to the proposed materials program. The RSC is required to meet at least quarterly and maintain minutes of each meeting.

Item 9 - Instrumentation

Some typical instruments required of licensees are specified by 32 Ill. Adm. Code 335.2010 and 335.2020. Based on the type of radioactive material requested in Item 7., specify the types of instruments that will be maintained at your facility and address the following:

A. Radiation Detection Instrument

A low-level monitoring instrument must be capable of detecting 1 microSievert per hour (µSv/hr) to 500 µSv/hr [0.1 millirem per hour (mrem/hr) to 50 mrem/hr] to perform contamination surveys. This type of monitoring instrument is required for

licenses authorizing the use of radioactive material for uptake, dilution and excretion studies (Subpart D); imaging and localization studies (Subpart E); radiopharmaceutical therapy (Subpart F); implant therapy (Subpart H); teletherapy (Subpart I); or as a sealed source for diagnostic purposes (Subpart G). The applicant should submit a completed Exhibit C for the low-level monitoring instrument to be used to meet the requirements of 32 Ill. Adm. Code 335.2020.

B. Radiation Measurement Instrument

A high-level monitoring instrument, such as an ionization chamber, must be capable of measuring rates over the range of 10 μSv/hr to 10 mSv/hr (1 mrem/hr to 1000 mrem/hr). This type of monitoring instrument is required for licensees authorized to use radioactive material for radiopharmaceutical therapy, implant therapy, low and high dose rate afterloader therapy, teletherapy or imaging and localization studies originating from an in-house Mo-99/Tc-99m generator program. The applicant should include a completed Exhibit C for the high-level monitoring instrument to be used to meet the requirements of 32 Ill. Adm. Code 335.2020.

Upon written request or by checking the box in Item 9 of the application form, pursuant to 32 Ill. Adm. Code 310.30, the Agency can grant an exception from this requirement for licensees who use only diagnostic radiopharmaceuticals and do not use Mo-99/Tc-99m generators.

C. Other Facility Instruments

Specify all radiation measuring/monitoring instruments to be used at your facility. This list shall include, but is not limited to, fixed area monitors and instruments for analysis of wipe tests. You must submit calculations to show that the instrumentation used to analyze wipe test samples is sufficiently sensitive to detect 2000 dpm. Appendix C contains information regarding minimum detectable activity calculations.

Note that one instrument that has sufficient sensitivity and range, such as a compensated G-M, may meet the requirements for both measurement and detection instruments. Please also note that when a required monitoring instrument is sent for repair, calibration or maintenance, the licensee must ensure that an equivalent, operable, calibrated monitoring instrument is available for use to meet the requirements of 32 Ill. Adm. Code 335.2020. The licensee must maintain copies of calibration records for loaner equipment.

Exhibit C is a form that may be used to describe the applicant's instrumentation. If this form is not used, then submit equivalent information.

Item 10 - Instrument Calibration and Operability Checks

A. Dose Calibrators

In accordance with 32 Ill. Adm. Code 335.2010(b), the licensee must ensure the proper operation of dose calibrators used to measure the amount of radioactivity per dose prior to administration to a patient. The following dose calibrator checks and calibrations are required by 32 Ill. Adm. Code 335.2010(b) to ensure instrument operability:

1. Constancy (day of use);
2. Linearity (at intervals not to exceed three months and after installation);
3. Accuracy (annually and after installation); and
4. Geometrical Variance (after installation).

These operability checks and calibrations are required following adjustment or repair of the dose calibrator in accordance with 32 Ill. Adm. Code 330.2010(d).

Although 32 Ill. Adm. Code 335.2010(c) indicates that dosage readings must be corrected if the linearity or geometry error exceeds 10 percent and the dose calibrator must be repaired or replaced if the accuracy or constancy error exceeds 10 percent, the licensee is still responsible for assuring that the combined total error does not result in a reportable or recordable event as defined in 32 Ill. Adm. Code 335.20. It would be prudent for the licensee to establish lower error limits (on the order of 5 percent) as levels that require notification to the RSO.

Appendix D contains a sample procedure for calibrating dose calibrators. Either indicate that you will use the procedure in Appendix D or submit an alternate procedure for Agency review.

B. Radiation Monitoring Instruments

In accordance with 32 Ill. Adm. Code 335.2020(d), the licensee must ensure that the monitoring instruments used to show compliance with 32 Ill. Adm. Code 335 are calibrated prior to first use, at intervals not to exceed 12 months thereafter and also following repair. Specify whether monitoring instruments will be calibrated by a service company specifically licensed to perform monitoring instrument calibrations as a customer service in accordance with 32 Ill. Adm. Code 335.2020(e)(4) or whether the applicant will calibrate its own instruments.

If monitoring instruments are to be calibrated by the applicant, then the applicant must submit the information requested in Appendix E. If a consultant or other licensed firm will perform the calibration of your monitoring instruments, then maintain a copy of the radioactive material license which authorizes that entity to perform monitoring instrument calibrations as a customer service.

In addition, 32 Ill. Adm. Code 335.2020(g) requires the licensee to check instrument operability by using a dedicated check source, and maintain records of these checks. These instrument operability checks are required to be performed on each day that the instrument is used; however, a record of these checks is required only after repair, battery change or instrument calibration and at intervals not to exceed three months.

For these instrument operability checks, the term dedicated check source means that:

1. The sealed source used must contain a radionuclide with a relatively long half-life (e.g., Cs-137, T ½ 30 years).

2. The sealed source used to check an instrument's operability must remain the same throughout the time period between instrument calibrations (e.g., the source must be the same model and serial number used previously for that particular model and serial number instrument).

   Note that this does not prohibit the licensee from using the same sealed source as the dedicated check source for more than one instrument. It only requires that the sealed source used initially by the licensee upon return of that instrument from repair or full calibration, must remain the same until that instrument is later calibrated.

Item 11 - Facilities and Equipment

Submit annotated diagrams of all areas in which radioactive material will be used or stored (e.g., *In vitro* laboratories, hot laboratories, imaging rooms, cardiac stress test rooms, therapy rooms, radioactive waste storage rooms, etc.). Sample diagrams can be found in Appendix F. Submitted diagrams should:

A. Specify the diagram scale. (All diagrams should be large enough to easily identify areas of interest within each room, such as dose preparation areas, generator/waste storage areas, package receipt areas, hot sinks, etc.)

B. Indicate the direction of north.

C. Clearly mark or identify all areas adjacent (above, beside and below) to radioactive material use/storage rooms or areas (e.g., offices, hallways, restrooms, outside, etc.).

D. Specify the building, floor, room number and principal use of each room or area.

E. Note the presence of shielding in rooms or areas on the diagram and indicate thickness and composition.

F. Specify any additional radiation safety equipment for rooms or areas such as fume hoods, L-blocks, remote handling equipment, storage and transport containers, brachytherapy source safes, portable shielding, etc.

G. Clearly identify all area(s) assigned for receipt, storage (including waste), preparation and measurement of radioactive material.

H. Specify all pertinent airflow rates and directions, room pressures, filtration equipment and monitoring instrumentation available in rooms or areas in which radioactive material could become airborne.

I. Indicate all lockable doors, storage containers and security measures for all use/storage locations for radioactive material.

J. For each permanent storage or use location, if the applicant does not own the use/storage facility/property, submit a letter from the owner of the facility/property verifying the owner is aware of the use/storage of radioactive material on this property. If the facility/property is owned by the applicant, so indicate.

Item 12 - Personnel Training Program

All individuals whose jobs may require them to access any portion of a restricted area must receive instruction as specified in 32 Ill. Adm. Code 400.120. Submit a description of the training that will be provided to all personnel who work with or in the vicinity of, radioactive material. This training description should include the form of training (e.g., formal course work, lectures), the frequency of training, the duration of training, the name of the individual providing the training, a sample of the training record to be maintained (or a description of such records content and the subject matter). As outlined in 32 Ill. Adm. Code 400.120, the training program, at a minimum, should be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, maintenance, housekeeping and security personnel, receive proper instruction in such items as:

A. Use and storage areas for radioactive material.

B. Potential hazards from radioactive material.

C. Radiological safety procedures appropriate to each individual's respective duties including ALARA.

D. Pertinent Agency regulations.

E. Pertinent terms and conditions of the license, including information and procedures submitted as part of the application.

F. The individual's obligation to report unsafe conditions.

G. Appropriate response to emergencies or unsafe conditions.

H. Each individual's right to be informed of his or her radiation exposure, including bioassay results.

I. An identification of locations where the licensee has posted or made available notices (i.e., Notice to Employees form KLA 001.01), copies of pertinent regulations and copies of pertinent licenses and license conditions (including the application and applicable correspondence), as required by 32 Ill. Adm. Code 400.

Regarding the frequency of personnel training, such training must be provided to personnel before assuming duties in or performing duties requiring access to, any portion of a restricted area; at intervals not to exceed 12 months as refresher training and whenever there is a significant change in duties, potential radiation hazards, regulations or the terms of the license.

Appendix Q contains a sample outline of an acceptable personnel training program. Either indicate that you will use the outline contained in Appendix Q or submit an alternate outline for Agency review.

Note: Additional information regarding radiation, its effects on humans, protection against radiation and how these items apply to individuals working in a medical facility can be found in NCRP Report Number 105.

Item 13 - Procedure for Ordering and Receiving Radioactive Material

Submit a description of your procedure for ordering and receiving radioactive materials (including receipt during off-duty hours) and for notifying responsible persons upon receipt of radioactive material. This procedure should be adequate to meet the requirements of 32 Ill. Adm. Code 340.960, to ensure that possession limits are not exceeded, to ensure that radioactive material is secured at all times against unauthorized removal, to ensure that radiation levels in unrestricted areas do not exceed the limits specified in 32 Ill. Adm. Code 340.310 and to ensure that all receipts are properly documented.

Security personnel, nursing personnel or any other individuals who receive packages of radioactive material during off-duty hours should be issued written procedures that detail receipt, examination and security for packages. Procedures should include notification procedures to be followed for packages found or suspected to be leaking and indicate the immediate steps to be taken to prevent the spread of contamination.

Appendix G contains a sample procedure and instructions for ordering and receiving radioactive material packages.

Item 14 - Procedure for Safely Opening Radioactive Material Packages

Submit your procedure for examining incoming packages for leakage, contamination or damage and for safely opening packages in accordance with 32 Ill. Adm. Code 340.960. Package monitoring should be performed as soon as practicable after receipt. This procedure may vary depending on the type and quantity of radioactive material received, but should, at a minimum, include instructions for surveying packages, wearing gloves while opening packages, checking packing material for contamination after opening and verifying the contents of packages of radioactive material, not only against the packing slip, but also against the amount, type and form of material ordered. Even though 32 Ill. Adm. Code 340.960 exempts certain packages from immediate monitoring, it is necessary that procedures be established for safely opening all radioactive material packages.

Appendix H contains a sample procedure for safely opening packages of radioactive material. Either indicate that you will follow the procedure contained in Appendix H or submit an alternate procedure for Agency review.

Item 15 - General Rules for the Safe Use of Radioactive Material

Submit the general safety instructions to be followed by all personnel while working with radioactive material. The instructions should:

A. Explain what safety apparel to wear, what equipment to use (e.g., wearing laboratory coats, eye protection and disposable gloves and using trays and shielding).

B. Indicate what personnel monitoring devices to use when handling radioactive material.

C. Specify limitations and conditions for handling liquid or unsealed sources of radioactive material and the safety equipment to use when working with them.

D. Specify the shielding or remote handling equipment to be used when handling beta and/or gamma emitting materials. For example, radiopharmaceutical kits should be prepared behind shielding and, in accordance with 32 Ill. Adm. Code 335.2060 and 335.2070, syringe shields must be used for the preparation and administration of patient doses.

E. Include procedures for the preparation and assay of patient doses.

F. Include guidance concerning security of radioactive material.

G. Provide instructions for movement of radioactive material between rooms, in halls or in corridors.

H. Provide guidance on waste disposal requirements.

I. Describe contamination control procedures including prohibitions against smoking, eating, drinking or the application of cosmetics and prohibiting the storage of personal items (food, drink, cosmetics, etc.) in areas where radioactive material is used or stored. In addition, include instructions to individuals for performing radiation monitoring of their hands, clothing, shoes, etc. after working with radioactive material.

For most programs, Appendix I contains a sample set of general rules for safe radioactive material use. Either indicate that you will follow the procedure contained in Appendix I or submit an alternate procedure for Agency review.

Item 16 - Emergency Procedure

Submit a copy of your emergency procedure. A copy of this procedure should be posted in all areas where radioactive material is used (including dose preparation and injection areas) and should:

A. Describe immediate action to be taken after an incident in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, area evacuation and spill containment). Actions to be taken for handling injured personnel who may be contaminated should also be addressed.

B. List the names and telephone numbers of the responsible persons (e.g., RSO) to be notified in case of an emergency. The Agency's 24-hour number should be included in this section (217/782-7860).

C. Instruct personnel on appropriate methods of re-entering and decontaminating contaminated areas.

D. Describe what action is to be taken in the event of fire, theft or loss involving radioactive material. This response must include the notification of this Agency in accordance with 32 Ill. Adm. Code 340.1210 and 340.1220.

Appendix J contains a sample emergency procedure. Either indicate that you will follow the procedure contained in Appendix J or submit an alternate procedure for Agency review.

Item 17 - Waste Disposal/Treatment

Radioactive material licensees are authorized to use the following methods for the disposal / treatment of radioactive waste:

A. Transfer to a person properly licensed to receive such waste (e.g., commercial waste disposal firms, see 32 Ill. Adm. Code 340.1010).

B. Release into the sanitary sewerage system in conformance with 32 Ill. Adm. Code 340.1030. Calculations for concentration of releases made must be submitted.

C. Release into the air in conformance with 32 Ill. Adm. Code 340.1060. Calculations for concentration of releases made must be submitted.

D. Disposal of scintillation fluid and animal tissue in conformance with 32 Ill. Adm. Code 340.1050.

Applicants may also be authorized to store waste containing or comprised of, radioactive material with a physical half-life of less than 90 days for "decay-in-storage" before disposal with the following provisions:

A. Radioactive waste to be disposed of shall be held for decay a minimum of ten half-lives.

B. Pursuant to 32 Ill. Adm. Code 340.510(a) and (b), radiation surveys shall be performed prior to disposal of the waste to ensure that the waste's radioactivity cannot be distinguished from background radiation levels. The package/container surface shall be surveyed with a radiation detection/measurement instrument set on its most sensitive scale, with no interposed shielding between the detector and the waste, in a low background radiation environment. Records of monitoring shall be maintained and shall include: date of disposal, date placed in storage, manufacturer, model and serial number of the survey instrument used, background radiation levels, measured radiation levels, and identity of the individual performing the monitoring. All radiation labels shall be removed or obliterated.

C. Generator columns shall be segregated from their shields and other waste and monitored separately to ensure decay to background levels prior to disposal.

D. The licensee is not relieved from complying with other applicable federal, state and local regulations governing any other toxic or hazardous property of these materials.

If authorization to dispose of radioactive materials by decay-in-storage is desired or a method different from those identified above (i.e., incineration) is to be used, detailed information regarding facilities, equipment and handling procedures must be submitted.

In addition, if the licensee plans to perform any treatment of radioactive waste (i.e., compaction) prior to transfer, detailed procedures should be submitted describing those operations.

Item 18 - Testing Sealed Sources for Leakage and/or Contamination

Testing of sealed sources for leakage and/or contamination shall be performed only by persons who are specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission (NRC), an Agreement State, or a Licensing State to perform such services. In establishing a program for testing for leakage and/or contamination in accordance with 32 Ill. Adm. Code 340.410, two alternatives are available from which to choose:

A. The services of a licensed consultant or commercial organization may be used to obtain test samples, evaluate the samples and report the results back to the applicant. In addition, a commercially available test kit may be used to obtain a test sample for subsequent analysis by a licensed service company. When using a licensed service, please note the licensee should maintain a copy of that company's license, which authorizes them to perform tests for leakage and/or contamination as a customer service.

B. The applicant may request authorization to perform tests for leakage and/or contamination, including sampling and analysis. If this option is chosen, then submit the information outlined in Appendix K for Agency evaluation.

Item 19 - Therapeutic Use of Radiopharmaceuticals

In addition to those procedures specified in the regulations and those identified as general safety precautions (Appendix I), submit an additional procedure for handling therapeutic radiopharmaceuticals and patients treated with therapeutic radiopharmaceuticals described in 32 Ill. Adm. Code 335 Subpart F. Although some therapy procedures are performed on an outpatient basis, these patients sometimes require hospitalization; therefore, the applicant's procedure should address the hospitalization, release and care of all radiopharmaceutical therapy patients. This procedure should describe:

A. Criteria and procedures for bioassay of personnel in accordance with 32 Ill. Adm. Code 335.5030(a)(11).

B. Procedures for performing baseline bioassay prior to administering therapeutic doses of I-131.

C. Procedures for opening containers of therapeutic doses of I-131 in an operating fume hood.

D. Procedures for controlling contamination, such as using disposable items (e.g., dishes, utensils, etc.).

E. Procedures for providing radiation safety instruction to nursing staff, patients and visitors.

F. Procedures for disposal/storage of items contaminated with radioactive material from the patient.

G. Procedures to be followed in case of emergency surgery or patient death.

Appendix L contains a sample procedure to be followed using therapeutic radiopharmaceuticals. Either indicate that you will follow the procedure contained in Appendix L or submit an alternate procedure for Agency review.

Item 20 - Bioassay

Bioassays are required by 32 Ill. Adm. Code 340.520 when individuals are likely to receive an intake in excess of 10% of the annual limit on intake. Bioassays are normally performed when individuals work with millicurie quantities of unsealed hydrogen-3, iodine-125 or iodine-131, depending on the chemical and physical form and the procedures followed and the equipment used that makes it possible for radioactive materials to be ingested, inhaled or absorbed into the body. The applicant should indicate the need for bioassay has been thoroughly considered and should describe the proposed bioassay program, if applicable. U.S. NRC Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" may be of assistance in preparing these descriptions.

Appendix M contains a sample procedure to be followed when performing radioiodine bioassay. If radioiodine is to be used, verify that procedures contained in Appendix M will be followed or submit an alternate procedure for Agency review.

Note: Significant thyroid uptakes have been detected in individuals who open and prepare I-131 therapeutic doses in liquid or capsule form. Bioassay should also be considered for personnel (e.g., radiation safety, nursing) who are involved in other aspects of therapy procedures.

Additional guidance for the management of therapy patients can be found in National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients who have Received Therapeutic Amounts of Radionuclides."

Item 21 - Sealed Sources for Brachytherapy

Submit a procedure for handling brachytherapy sources and patients treated with brachytherapy sources as described in 32 Ill. Adm. Code 335 Subpart H. This procedure should describe:

A. Special precautions to be used while handling sealed sources.

B. Procedures for providing instruction to nursing staff, patients and visitors.

C. Procedures for preventing inadvertent disposal of brachytherapy sources.

D. Procedures to be followed in case of emergency surgery or patient death.

E. Procedures to be followed for the transport of sources from storage to the site of administration. This should include a description of the transport container.

Appendix N contains a sample procedure to be followed when treating patients with brachytherapy sources. Either indicate that you will follow the procedure contained in Appendix N or submit an alternate procedure for Agency review.

Item 22 - Procedure for Use of Radioactive Gas/Volatile Material

The use of radioactive gas or volatile material (e.g., Xe-133 gas or I-131) requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive effluent in restricted and unrestricted areas, including effluent released to the atmosphere. *Each applicant who wishes to use radioactive gas or volatile material must submit unrestricted area concentration calculations to the Agency in support of that request as well as document personnel exposures as a result of restricted area releases in accordance with 32 Ill. Adm. Code 340.230 and 340.240. If ventilation systems are used in conjunction with radioactive gas/volatile material, procedures for use and maintenance of these systems should be included in the application.*

Appendix O contains sample calculations. The applicant should refer to the sample calculations in Appendix O to compile information in support of a request to use radioactive gas/volatile material such as Xe-133/I-131.

Item 23 - Personnel Monitoring Devices

32 Ill. Adm. Code 340.520(a) specifies when personnel monitoring equipment is necessary. On the application, indicate the type(s) of personnel monitoring device(s) to be used (e.g., whole-body and/or finger device) and the frequency at which the device will be exchanged and evaluated. Normally, in addition to whole-body film or thermoluminescent dosimeter (TLD) badges or optically stimulated luminescent (OSL)

dosimeters , any person who elutes generators, prepares doses, administers radiopharmaceuticals, prepares sealed source applicators, inserts sealed sources, etc. **must wear a ring film badge or TLD unless it can be demonstrated by calculation and/or monitoring results that the radiation exposure is not likely to exceed 10% of the applicable limits set forth in 32 Ill. Adm. Code 340.210.** Finger badges should be turned to the inside and worn on the finger most likely to receive the greatest radiation exposure. In addition, each applicant using a film badge or TLD service must ensure that the service meets the requirements of 32 Ill. Adm. Code 340.510(c).

If direct reading dosimeters (pocket ionization chambers) are used in the program, indicate the conditions under which they will be used, each dosimeter's useful range, frequency of reading and recording dosimeter readings and the procedure for maintaining and calibrating the dosimeters. Please note, however, that direct reading dosimeters are not an acceptable means of primary dose assessment when personnel monitoring is required by 32 Ill. Adm. Code 340. Such required monitoring must be by film badges, TLD or OSL dosimeters. Information from this section, Item 20, Item 22 and 32 Ill. Adm. Code 340.220 should be considered in determining requirements for the summation of doses.

Appendix P contains a sample procedure for use and calibration of direct reading dosimeters. If you intend to use direct reading dosimeters, either indicate that you will follow the procedure contained in Appendix P or submit an alternate procedure for Agency review.

Item 24 - License Fees

Refer to 32 Ill. Adm. Code 331 and the appropriate fee schedule to determine the correct fee. Applications will NOT be processed until the correct fee is received by this Agency. Questions concerning fees should be directed to the Materials Licensing unit staff.

Item 25 – Financial Assurance

(((THIS NEEDS TO BE COMPLETED)))

Item 26 - Certification

The application must be signed and dated by the applicant, if acting as an individual or by an individual who is authorized by management to sign on behalf of the facility. A statement signed by facility management granting authority to sign license requests and related documents is required for applications not signed by an officer or the administrator of the facility. Unsigned applications will be returned for proper signature.

IV. LICENSE AMENDMENT

Licensees are required to conduct their programs in accordance with statements, representations and procedures contained in the license application and supporting documents. The license must be amended if the licensee plans to make any changes in the facilities, equipment, procedures, authorized users, RSO or radioactive material used.

Applications for license amendments should be filed on the application form or in letter form. The application must identify the license by number and clearly describe the exact nature of the changes, additions or deletions requested. References to previously submitted information and documents must be clear and specific and identify the applicable information by date, page and paragraph. *For medical institutions, in accordance with 32 Ill. Adm. Code 335.1030(b)(4), amendment requests must include a statement verifying that the radiation safety committee has reviewed and approved the amendment request.* This documentation must also be maintained on file for inspection. An original and two copies of the application for amendment should be prepared. The original and one copy must be submitted and the licensee must retain one copy and all attachments with the license file. Licensees must conduct their program in accordance with their current license until said amendment is issued.

V. LICENSE RENEWAL

An application for license renewal must be received by the Agency at least 30 days prior to the expiration date. Expedited renewals using form IL-473-0037 may also be used for programs without many changes since the previous renewal. Applicants using this option should review their program against the regulations, the license and the license conditions with all active amendments, your operating procedures and the ALARA program to ensure that your program is reflective of current operations for the material to be used. Renewals using the expedited option should be filed 120 days prior to the expiration date. This filing will ensure that the license does not expire until final action on the application has been taken by the Agency as provided for by 32 Ill. Adm. Code 330.330.

Renewal applications must be filed on form IL 473-00272 or IL 473-0337, appropriately supplemented, contain complete and up-to-date information about the applicant's program and meet all licensing and regulatory requirements in effect at the time of renewal. Renewal applications in their entirety using form IL 473-00272 should be submitted without reference to documentation and information submitted previously, except for previously approved users. If such references cannot be avoided, they are acceptable provided:

A. The reference is made in response to a particular item of required information (e.g., radiation instrument calibration procedures);

B. The reference is clear and specific (e.g., title of document, date of submission, page and paragraph); and

C. The referenced document contains all information required for a particular item at the time of renewal.

VI. LICENSE TERMINATION

A licensee may request termination of a radioactive material license at any time. To terminate a license, the licensee must meet the requirements of 32 Ill. Adm. Code 330.320(d), which include:

A. Transfer or disposal of all licensed radioactive material in the licensee's possession in accordance with 32 Ill. Adm. Code 340;

B. Completion of IEMA form KLM.007, "Certificate - Termination and Disposition of Radioactive Material" (see Exhibit D); and

C. Performance of radiation monitoring or the equivalent in accordance with 32 Ill. Adm. Code 330.320(d)(1)(E).

Submit the completed IEMA Form KLM.007 and a copy of any applicable radiation monitoring records to the Agency at least 30 days before the expiration date of the license or upon termination of all licensed activities. The Agency reserves the right to perform confirmatory monitoring of licensed facilities prior to termination.

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APPENDIX A

RETENTION OF DOCUMENTS

I. PERMANENT JOB SITES

Document	Retention Interval
32 Ill. Adm. Code	Until termination of license
License, all active amendments and supporting documents (including the application)	Until termination of license
Annual Radiation Protection Program and ALARA Reviews	5 Years
Receipt, Transfer and Disposal	Until disposal is authorized by the Agency
Survey Instrument Calibration	5 Years
Tests for Leakage and/or Contamination	5 Years
Inventories	5 Years
Utilization Logs	Until disposal is authorized by the Agency
Inspection and Maintenance	Until disposal is authorized by the Agency
High Radiation Area Control Devices or Alarm Systems	Until disposal is authorized by the Agency
Training and Testing Records	Until disposal is authorized by the Agency or 3 years after termination of employment
Personnel Monitoring Records and Pocket Dosimeter Readings	Until disposal is authorized by the Agency
Pocket Dosimeter Calibrations	5 Years

I. PERMANENT JOB SITES (continued)

Document	Retention Interval
Radiation Monitoring Records	5 years or until disposal is authorized by the Agency if a survey was used to determine an individual's exposure

II. TEMPORARY JOB SITES

Document	Retention Interval
License and Active Amendments	Until termination of job
Operating/Emergency Procedures	Until termination of job
Latest Leak Test Result	Until termination of job

APPENDIX B

GUIDE TO SI UNITS

RADIATION DOSE EQUIVALENT

OLD *(rem)*	NEW *(sievert)*
0.1 mrem	1 µSv
0.25	2.5
0.5	5
0.75	7.5
1.0 mrem	10 µSv
2.5	25
10 mrem	100 µSv (0.1 mSv)
100 mrem	1 mSv
500 mrem	5 mSv
1 rem	10 mSv
1.5 rem	15 mSv
5	50
10 rem	100 mSv
15 rem	150 mSv
50 rem	500 mSv
100 rem	1 Sv

AMOUNT OF RADIOACTIVE MATERIAL

OLD Ci *(curie)*	NEW Bq *(becquerel)*
1 pCi	37 mBq
27 pCi	1 Bq
1 nCi	37 Bq
27 nCi	1 kBq
1 µCi	37 kBq
27 µCi	1 MBq
1 mCi	37 MBq
27 mCi	1 GBq
1 Ci	37 GBq
27 Ci	1 TBq

SURFACE ACTIVITY LEVELS

µCi/cm^2	Bq/cm^2	(kBq/m^2)
10^{-6}	0.037	0.37
3×10^{-6}	0.1	0.1
10^{-5}	0.37	3.7
3×10^{-5}	1	10
10^{-4}	3.7	37
3×10^{-4}	10	100
10^{-3}	37	370
3×10^{-3}	100	1000
10^{-2}	370	3700

(1 m^2 = 10^4 cm^2)

CONVERSIONS

100 rem = 1 Sv

100 rad = 1 Gy (gray)

1 ton = 1 Mg

1 ton = 1000 kg

1 kg = 1000 g

1 MBq/ton = 1 Bq/g

RADIATION DOSE RATES

µSv/h, mSv/h

e.g.,

7.5 µSv/h

25 µSv/h

DERIVED AIR CONCENTRATION (DAC)

Units: Bq m^{-3}

Conversion:

µCi cm^{-3} x 3.7 x 10^{10} = Bq m^{-3}

$$\frac{\text{dpm m}^{-3}}{60} = \text{Bq m}^{-3}$$

CONCENTRATION IN SOLUTION

µCi	kBq/dm^3 (kBq/l)
1	37
10	370
100	3700

1 m^3 = 10^3 dm^3 = 10^3 l or 10^3 L

1 mBq/m^3 = 1 kBq/dm^3

PREFIXES FOR UNITS:

a	atto	10^{-18}	
f	femto	10^{-15}	
p	pico	10^{-12}	trillionth
n	nano	10^{-9}	billionth
µ	micro	10^{-6}	millionth
m	milli	10^{-3}	thousandth

k	kilo	10^3	thousand
M	mega	10^6	million
G	giga	10^9	billion
T	tera	10^{12}	trillion
P	peta	10^{15}	
E	exa	10^{18}	

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APPENDIX C

SAMPLE MINIMUM DETECTABLE ACTIVITY CALCULATIONS

Several references contain discussions of counting statistics for radiation measurements. For purposes of this guide, the discussion contained in NCRP Report No. 58 appears to be the simplest to use. The formula we recommend is the one for determining a measurement at the 95% confidence level. The formula for this level is:

$$LLD = \frac{2.71 + 4.65\sqrt{B}}{EFF}$$

where:

LLD	=	Lower Limit of Detection (dpm, divide by 2.2 E+6 for μCi)
B	=	Background counting rate (counts/time) and
EFF	=	Counting efficiency.

The sample counting time and background counting time must be equal. The counting efficiency must be determined by using a standard source of known activity that emits photons of approximately the same energy as the contaminant to be detected. The counting rate for the standard is divided by the standard activity to determine the counting efficiency. When dividing, the two values must be in compatible units. A standard activity in μCi must be converted to dpm by multiplying by a factor of 2.2E+6.

For a copy of the full discussion of the theory and limitations of this test, refer to pages 307-311 in NCRP Report No. 58, A Handbook of Radioactivity Measurement Procedures, issued February 1, 1985 by the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Bethesda, MD 20814.

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APPENDIX D

PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

All radiopharmaceuticals will be assayed for activity to an accuracy of ±10% using an ionization type dose calibrator. The dose calibrator must be checked for accurate operation at the time of installation, after repair or adjustment and periodically thereafter as described in this procedure. The periodic operational tests include the following:

A. Dose Calibrator Constancy

Daily or before each use of the dose calibrator, measure and record the apparent activity of a long-lived standard radionuclide, such as Cs-137, at all the radionuclide settings to be used that day. Choose a source with a minimum activity of 1.85 MBq (50 μCi) or 370 kBq for Ra-226 (10 μCi).

Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source, such as Cs-137, Co-60 or Ra-226, using a reproducible geometry each day before using the dose calibrator. Use the following procedure:

1. Assay each reference source using the appropriate dose calibrator setting (i.e., Cs-137 setting for Cs-137).

2. Measure the background level at the same dose calibrator setting and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

3. Log the background levels.

4. Indicate the predicted activity of each source based upon decay calculations and the certified activity provided for the reference source.

5. Repeat the procedure for the Cs-137 source for all of the radionuclide settings to be used that day.

6. Any dose calibrator instrument setting reading that differs by ±10% from the reading recorded at the most recent accuracy test for that setting will require the individual performing the test to immediately notify the RSO of suspected malfunction of the dose calibrator.

B. Dose Calibrator Linearity

Linearity means that the dose calibrator is able to indicate the correct activity over the range of use of that dose calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the largest dose to be injected.

1. Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator and subtract background level to obtain net activity in mega-becquerels (millicuries). Record the date, time to the nearest minute and net activity. This first assay should be done in the morning, for example, 8 a.m.

b. Repeat Item B(1)(a) at time intervals of 6, 24, 30 and 48 hours after the initial assay.

c. Using the 30 hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, 30 and 48 hours using the decay equation in Appendix E, Section E.3, or by using the following table (Note: You must use the decay equation instead of the correction factors if the 30-hour assay is not performed on time.):

Assay Time (hrs)	Correction Factor
0	32
6	16
24	2
30	1
48	0.125

Example: If the net activity measured at 30 hours was 15.625 millicuries, then the predicted activity for 6 and 48 hours would be 15.625 mCi x 16 = 250 mCi and 15.625 mCi x 0.125 = 1.95 mCi, respectively.

d. Calculate the variance between the measured net activity for each time interval versus the predicted activity. For example, using the data from the example in B.1.c. above, the variance for the 6-hour setting is 250 mCi - X mCi measured.

e. The activities should be within $\pm$10% of the calculated activity if the dose calibrator is linear and functioning properly. Errors greater than $\pm$10% indicate the need for repair or adjustment of the dose calibrator.

f. If dose calibrator linearity cannot be corrected, an aliquot of the eluate that can be accurately measured will be assayed. The need for correction of measured activity must be clearly indicated on or near the dose calibrator.

2. Shield or Sleeve Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them. The calibration and linearity test must be performed in accordance with the manufacturer's instruction manual. The following records must be maintained:

Calibration Procedure -

a. Record the date and time to the nearest minute.

b. Record the net activity.

c. Record all sleeve numbers and indicated activities.

d. Record "equivalent decay times" for each sleeve.

e. Identity of the individual performing the test.

Linearity Test Procedure -

a. Record the date and time to the nearest minute.

b. Record the net activity.

c. Record all sleeve numbers and indicated activities.

d. Record deviations between measured net activity and predicted activity. If the deviation exceeds 5%, appropriate correction factors must be recorded and available on or near the dose calibrator.

e. Identity of the individual performing the test.

C. Dose Calibrator Accuracy

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST), formerly National Bureau of Standards (NBS), or by the supplier who has compared that source to a source that was calibrated by the NIST. Certified sources are available from the NIST and from many radionuclide suppliers. At least three sources must be used Co-57, Ba-133 and Cs-137. The regulations require these sources to have a minimum activity of 3.7 MBq (100 μCi) for both Cs-137 and Ba-133 and 37 MBq (1 mCi) for Co-57.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.

2. Repeat step C(1) for a total of 3 determinations and average the results.

3. The average activity determined in step C(2) should agree with the certified activity of the reference source within ±10% after decay corrections.

4. Repeat the above steps for the other radionuclide reference standards and record these measurements.

5. Calibration checks which do not agree within ±10% indicate that the dose calibrator should be repaired or adjusted. If this is not possible, a calibration factor shall be calculated for use during routine assays of radionuclides. The need for correction of measured activity must be clearly indicated on or near the dose calibrator.

6. At the same time the dose calibrator is being initially calibrated with the NIST traceable standards, place a long-lived source in the dose calibrator, set the dose calibrator, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.) and record the readings. These values will later be used to check dose calibrator calibration at each setting (after correcting for decay of the long lived source), without requiring more certified standards. A log of these initial and subsequent readings will be maintained.

7. Put a sticker on the dose calibrator that indicates when the next accuracy test is due.

D. Geometrical Variation

Geometrical Variation is a measure of the change in the indicated activity with change in volume or configuration of the sample. This test shall be done using a syringe that is normally used for injections. If the specific license authorizes the use of generators and radiopharmaceutical kits, the test will also be done using a vial similar in size, shape and construction to the radiopharmaceutical kit vials normally used under the license. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If these are not used, the procedure will be changed so that your syringes and vials are tested throughout the range of volumes commonly used under the license. To measure variation with volume of liquid, a 30 cc vial containing 2 mCi of Co-57 or other appropriate radionuclide, gently mixed, in a volume of 1 ml will be used.

1. Assay vial at the appropriate dose calibrator setting and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20 and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake

vial to mix contents and assay as in step 1.

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for dose calibrator accuracy) and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02 and 2.00 mCi are measured for 4, 8 and 10 ml volumes respectively and 10 ml is the reference volume selected, then

$$4 \text{ ml Volume CF} = \frac{2.04}{2.00} = 1.02$$

4. Either calculate or plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows: True Activity = Measured Activity (x) Correction Factor where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30 cc vial and a correction factor may be calculated.

7. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower energy radionuclides such as I-125. Hence, adequate correction factors shall be calculated and used for syringes made of such different materials.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

If any correction factors are greater than 1.1 or less than - 0.90 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". If this is necessary, label the table or graph "syringe geometry dependence" and note the date of the test and the model and serial number of the dose calibrator.

In addition to these tests, the dose calibrator shall be inspected on a quarterly basis to ascertain that the measurement chamber liner is in place and that the dose calibrator zero is properly set according to the manufacturer's instructions.

In accordance with 32 Ill. Adm. Code 335.2010, the RSO shall review and sign the records for all dose calibrator geometry, linearity and accuracy test results.

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APPENDIX E

METHOD FOR CALIBRATING RADIATION DETECTION/MEASUREMENT INSTRUMENTS

1. Application For a Licensee to Perform Radiation Detection/Measurement Instrument Calibrations

   When radioactive material is used to calibrate radiation detection/measurement instruments, the person or organization performing the calibration must be specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

   An application for a licensee to perform radiation detection/measurement instrument calibrations should contain the following information:

   a. The manufacturer's name and model of the source(s) to be used.

   b. The radionuclide and activity of the radioactive material contained in the source(s).

   c. The accuracy of the source(s) activity; documentation that the determination of each source activity is traceable to the National Institute of Standards and Technology - NIST (previously National Bureau of Standards - NBS).

   d. A description of the facilities to be used.

   e. The name and applicable experience of each individual who will perform the calibrations.

   f. Calculations related to the calibration procedures.

   g. The step-by-step calibration procedures, including associated radiation safety procedures.

   h. Copies of records that will be maintained (see Item 4).

   i. Verification that the requirements outlined in this appendix will be followed.

2. Recommended Methods For Calibration of Radiation Detection/Measurement Instruments

The calibration of radiation detection/measurement instruments shall be performed in accordance with the following:

a. The radionuclide sources used for calibration shall approximate point sources.

b. The source activities shall be traceable* within ±5% accuracy to the NIST (previously NBS) calibrations.**

c. The frequency of calibration shall be at intervals not to exceed one year and after servicing/repair.

d. Each scale of the radiation detection/measurement instrument shall be calibrated at least at two points such that: (a) one point is in each half of the scale; and (b) the two points are separated by 50-60% of full scale. Logarithmic and digital readout radiation detection/measurement instruments with only a single readout scale shall be calibrated, at a minimum, at one point near the midpoint of each decade.

e. The exposure rate measured by the radiation detection/measurement instrument should not deviate more than ±10% from the calculated or known value for each point checked. (Read appropriate section of the radiation detection/measurement instrument manual to determine how to make necessary adjustments to bring the radiation detection/measurement instrument into calibration.) Readings within ±20% will be considered acceptable if a calibration chart or graph is prepared and attached to the radiation detection/measurement instrument. If the radiation detection/measurement instrument cannot be adjusted so that each reading falls within the ±20% range, it shall be taken out of service and sent to the manufacturer or to a qualified radiation detection/measurement instrument laboratory for repair.

---

* For purposes of this document, the amount of activity in a source is said to be traceable to a national standard when its activity was determined by comparison with a source of the same radionuclide (or a proper simulated source, isotopically) the activity of which is certified by the NIST.

** In lieu of using a traceable radioactive source, a transfer instrument traceable to the NIST, within ±5%, may be used as an alternative standard. For purposes of this document, a transfer instrument shall meet the definition as contained in the American National Standard Institute publication, ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration."

NOTE: Sources of cobalt-60, cesium-137, or radium-226 are appropriate for use in calibrations. The radioactivity of the calibration standard should be sufficient to calibrate the radiation detection/measurement instruments on all ranges, or at least up to 1 Roentgen per hour on the higher range radiation measurement instruments. If there are higher ranges, they should be checked for operation and approximately correct response to radiation.

f. If an electronic device is used to calibrate instruments, the instrument must still be checked for response to a known source of radiation.

3. Use of a Reference Check Source for Operational Checks

A reference check source of a long half-life (e.g., greater than five years) shall be used to obtain a radiation detection/measurement instrument response by the licensee. The reading shall be taken with the check source placed in a specific geometry relative to the detector and:

a. Shall be taken before use on each day the instrument is used;

b. Shall be taken after calibration by the licensee or after return to the licensee of a radiation detection/measurement instrument sent for calibration by a specifically licensed firm authorized to perform radiation detection/measurement instrument calibrations as a customer service;

c. Shall be taken after maintenance and/or each battery change; and

d. Shall be taken at least quarterly.

If any operational check reading using the reference check source, with the same geometry, is not within $\pm$20% of the reading measured immediately after calibration (or upon receipt from a calibration firm), the radiation detection/measurement instrument shall be removed from service and recalibrated.

4. Records

Records for Items 2, 3.b, 3.c and 3.d of this procedure shall be maintained.

a. Records for Item 2 shall include, at a minimum:

1) Radionuclide used;
2) Activity and assay date of source;
3) Present activity;
4) Calculated and measured radiation values, including the percent of difference;
5) Respective distance from source for each calculated and measured radiation value;

6) Necessary scale correction factors (required if calculated and measured radiation values do not agree within ±10%);
7) Make, model and serial number of radiation detection/measurement instrument being calibrated;
8) Name of individual performing the calibration; and
9) Date radiation detection/measurement instrument calibration was performed.

b. Records for Items 3.b, 3.c and 3.d of this procedure shall include, at a minimum:

1) Radionuclide used;
2) Activity and assay date of the radionuclide used;
3) Reading of check source at time of calibration;
4) Geometry of check source relative to detector (position);
5) Date of calibration;
6) Make, model and serial number of the radiation detection/measurement instrument;
7) Date reference check was performed; and
8) Name of individual who performed the reference check.

5. Use of Inverse Square Law and Radioactive Decay Law

a. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specific date by the manufacturer or National Institute of Standards and Technology (NIST).

1) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

2) The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

b. INVERSE SQUARE LAW:

S (R_1) (R_2)

* - - - - -P_1

* - - - - - - - - -P_2

Exposure rate at P_2:

$$R_2 = \frac{(P_1)^2 x (R_1)}{(P_2)^2}$$

where:

S is the point source

R_1 and R_2 are the exposure rates at P_1 and P_2 in the same units (e.g., mR/hr or R/hr).

P_1 and P_2 are the distances from the point source in the same units (e.g., centimeters, meters, feet, etc.)

c. RADIOACTIVE DECAY LAW:

$R_t = R_o\, e^{-(0.693\, t\, /T_{1/2})}$

where:

R_o and R_t are in the same units (e.g., mR/hr or R/hr)

R_o is exposure rate on specified calibration date (i.e., time zero)

R_t is exposure rate "t" units of time later

$T_{1/2}$ and t are in the same units (e.g., years, months, days, etc.)

$T_{1/2}$ is the half-life of the radionuclide

t is the time elapsed between the source calibration (assay) date and the radiation detection/measurement instrument calibration date (i.e., present time)

d. Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1985. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1987 (2.0 years later)?

1) Output at 1 foot, 2.0 years after calibration date:

$R_{(1\ ft)} =$ 100 mR/hr $[\exp^{-((0.693 \times 2.0)/5.27)}]$

$=$ 100 mR/hr (0.77)

$=$ 77 mR/hr at 1 foot on March 10, 1987

2) Output at 3 feet, 2.0 years after calibration date:

$$R_{(3\ ft)} = \frac{(1\ foot)^2}{(3\ feet)^2}\ (77mR/hr)$$

$=$ 1/9 (77 mR/hr)

$=$ 8.6 mR/hr at 3 feet on March 10, 1987

APPENDIX F

SAMPLE FACILITY DIAGRAMS

3rd Floor Imaging Room 3E-72

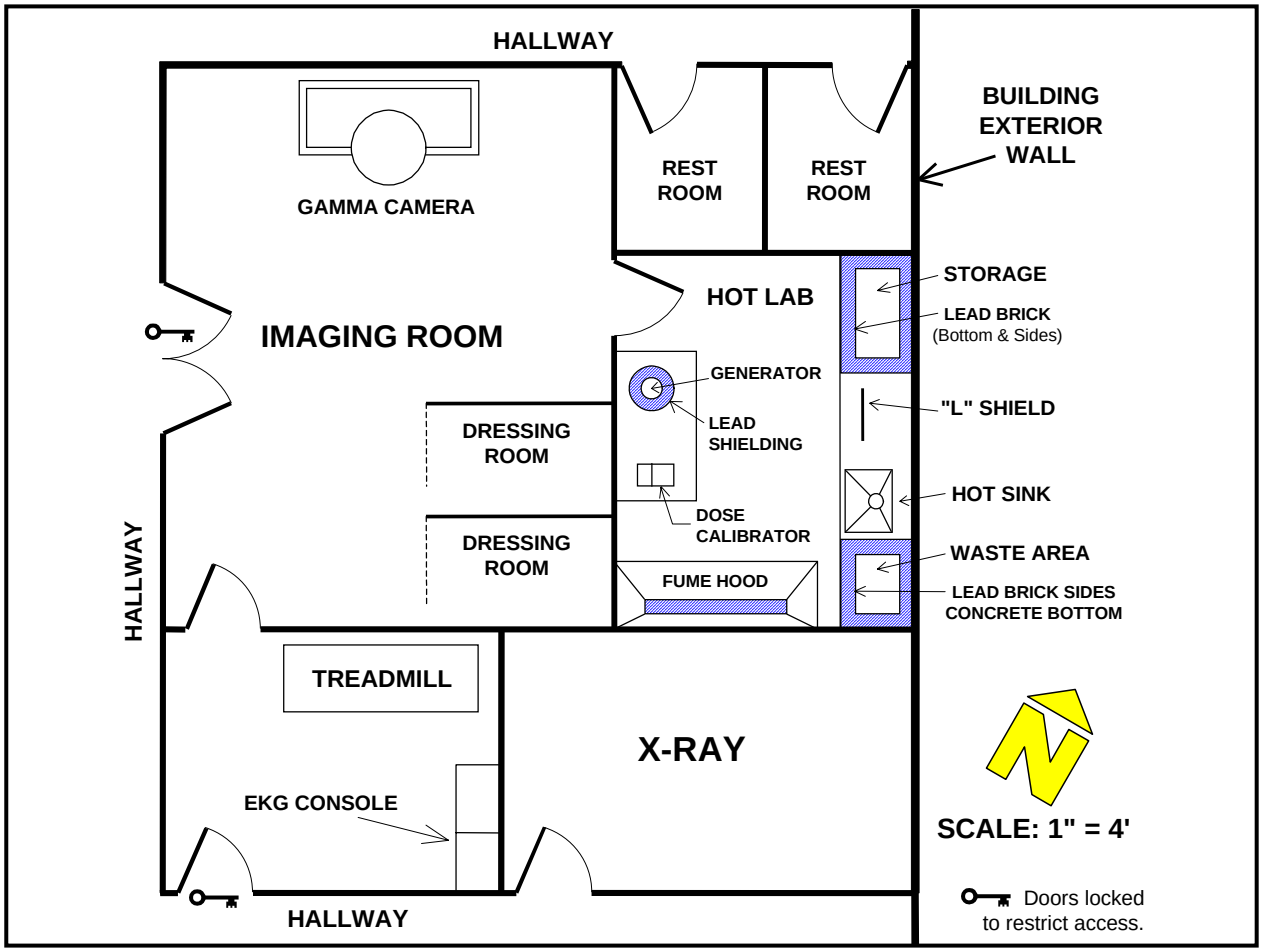

FIGURE 1

APPENDIX F (continued)

SAMPLE FACILITY DIAGRAMS

3rd Floor Imaging Room 3E-72

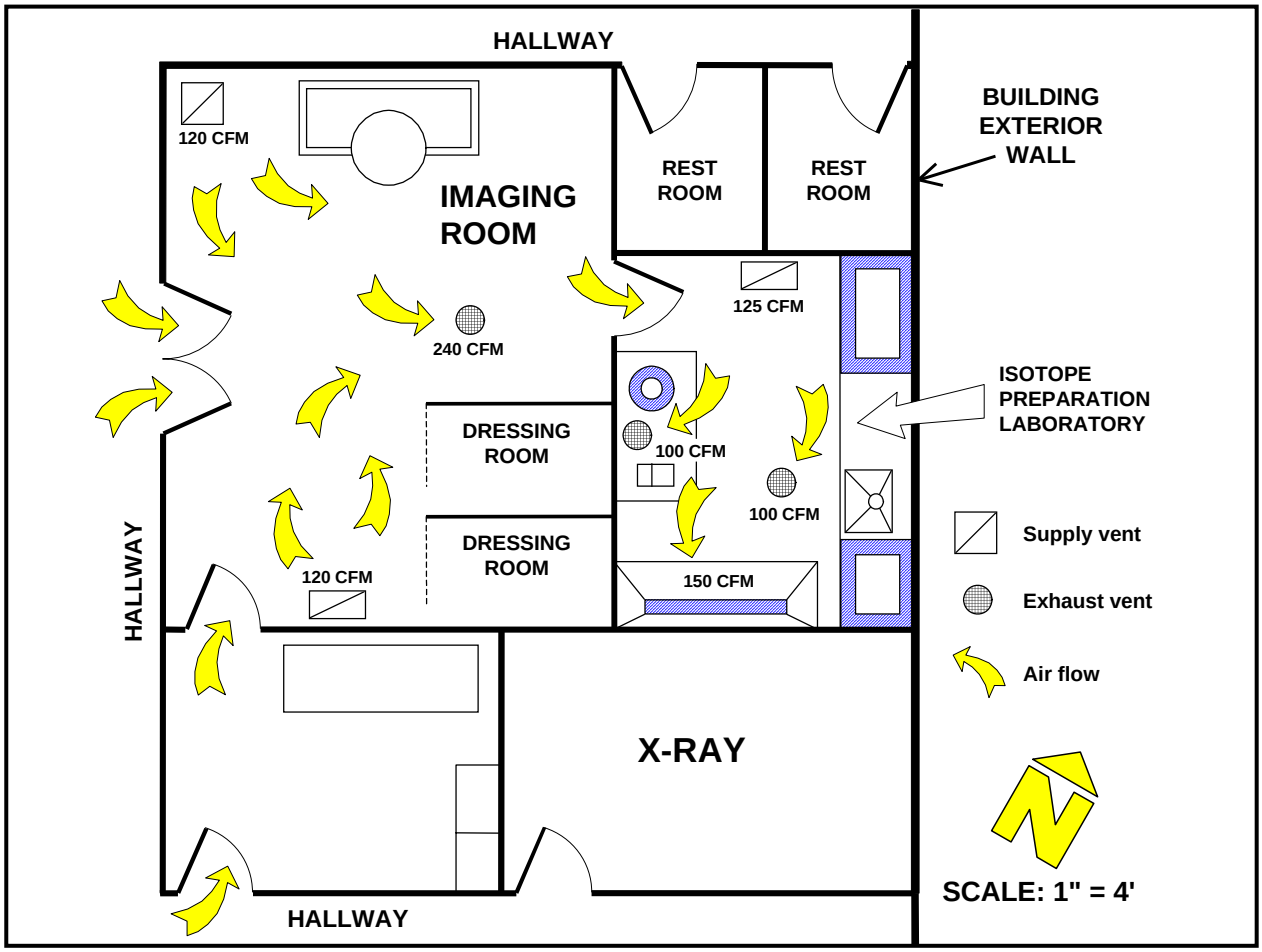

FIGURE 2

APPENDIX G

SAMPLE PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

A. The Radiation Safety Officer (RSO) or designee must place all orders for radioactive material and must ensure that the requested material and quantities are authorized by the license and that possession limits are not exceeded.

B. During normal working hours, carriers must be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

C. During off-duty hours, security personnel or other designated trained personnel must accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below.

SAMPLE MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: John Jones, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

If the package is wet or appears to be damaged, immediately contact the hospital's RSO. Ask the carrier to remain at the hospital until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between 4:30 P.M. and 7:00 A.M. or on Sundays shall be signed for by the Security guard on duty or other designated trained personnel and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package in the hot lab (or designated secured area) and relock the door.

RADIATION SAFETY OFFICER (RSO):_____

OFFICE PHONE:_____

HOME PHONE:_____

ILLINOIS EMERGENCY MANAGEMENT AGENCY 24-HOUR PHONE: (217) 782-7860

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APPENDIX H

PROCEDURE FOR SAFELY OPENING RADIOACTIVE MATERIAL PACKAGES

For packages received under the specific license, authorized individuals shall implement procedures for opening each package as follows:

1. a. Put on gloves to prevent hand contamination;

   b. Visually inspect the package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop and notify the Radiation Safety Officer (RSO);

   c. Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form radioactive material as defined in 32 Ill. Adm. Code 310.25;

      AGENCY NOTE: Labeled means labeled with a Radioactive White I, Yellow II or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

   d. Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 32 Ill. Adm. Code 341.25, as listed in 49 CFR 173.435; and

   e. Monitor all packages known to contain radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet or damaged.

2. The monitoring required by Item 1 above shall be performed as soon as practicable after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet or damaged. If a package is received after working hours and has no evidence of degradation of package integrity, the package shall be monitored no later than three (3) hours from the beginning of the next working day.

3. Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on bottle or syringe holder). Check integrity of the final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that the shipment does not exceed license possession limits. If anything is other than expected, stop and notify the RSO.

4. Survey the packing material and packages for contamination before discarding. If

contamination is found, treat as radioactive waste. If no contamination is found, obliterate all radiation labels prior to discarding in regular trash.

5. Maintain records of receipt, package survey and wipe test results.

6. The final carrier and the Agency shall be immediately notified by telephone and shall confirm the initial contact within 24 hours by overnight letter or telefacsimile to the Agency, when:

    a. Removable radioactive surface contamination exceeds the limits of 32 Ill. Adm. Code 341.10(b); or

    b. External radiation levels exceed the limits of 32 Ill. Adm. Code 341.10(b).

APPENDIX I

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive material is used.

2. Wear disposable gloves at all times while handling radioactive material or potentially contaminated items.

3. Monitor hands and clothing, with a low-level monitoring instrument (e.g., G-M survey meter), for contamination after each procedure or before leaving the area.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances when their use would compromise the patient's well-being (such as some pediatric cases).

5. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink or personal items in any area where radioactive material is stored or used.

7. a. Assay each patient dose in the dose calibrator prior to administration. Notify the authorized user if any doses differ from the prescribed dose by more than $\pm$10% and do not use unless an authorized user grants written approval.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form and the activity vs. the order written by the physician who will perform the procedure.

8. Secure all areas where radionuclides are stored when unattended.

9. Wear whole-body personnel monitoring devices (film badge, TLD or OSL) at all times while in areas where radioactive material is used or stored. These must be worn at chest or waist level where the highest exposure is expected.

10. Wear film or TLD finger badges, turned inward towards material, during elution of generator and preparation, assay and injection of radiopharmaceuticals. Finger badges are worn on the finger likely to receive the most dose.

11. Dispose of radioactive waste only in specially designated receptacles.

12. Never pipette by mouth.

13. Survey generator, kit preparation and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

14. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity and radiation level if applicable.

15. Always transport radioactive material in shielded containers.

APPENDIX J

EMERGENCY PROCEDURE

1. **MINOR SPILLS:**

   a. NOTIFY: Notify persons in the area that a spill has occurred.

   b. PREVENT THE SPREAD: Cover the spill with absorbent material and prevent access to the area by unauthorized personnel.

   c. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent material. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

   d. SURVEY: With a low range monitoring instrument (e.g., thin window, G-M survey meter) check the area around the spill, hands and clothing for contamination.

   e. REPORT: Report incident to the Radiation Safety Officer (RSO).

2. **MAJOR SPILLS:**

   a. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

   b. PREVENT THE SPREAD: Cover the spill with absorbent material, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

   c. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

   d. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

   e. CALL FOR HELP: Notify the RSO immediately.

f. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the RSO. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water. Injured persons should be decontaminated and first aid performed as necessary. If life threatening injuries are present, the individual should be given immediate life-saving first aid and transported to a hospital for further medical treatment regardless of any contamination present. The hospital should be given prior notification that the patient is contaminated so that the appropriate controls can be implemented.

3. **EXPOSURE TO SOURCES OF RADIATION**

Terminate the source of exposure and prevent others from being exposed. Use additional shielding as needed. Notify the RSO so the nature and extent of exposure can be determined. Seek medical attention if severe exposure is suspected.

4. **LOSS, THEFT OR DAMAGE TO A SOURCE OF RADIOACTIVE MATERIAL**

In addition to following the applicable procedures outlined above, notify the RSO immediately and the Illinois Emergency Management Agency (217) 782-7860.

RADIATION SAFETY OFFICER (RSO):_____

OFFICE PHONE:_____ HOME PHONE:_____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

_____

APPENDIX K

TESTING SEALED SOURCES FOR LEAKAGE AND/OR CONTAMINATION

Applicants who wish to perform their own tests for leakage (leak tests) and/or contamination, including procurement and the analysis of the test samples, must submit the following descriptive information in support of the application:

1. Describe all instrumentation that will be used for the analysis of the test samples. The descriptive information should include:

    a. The manufacturer, model and serial number of each instrument;

    b. The types and energies of detectable radiation, as it pertains to each instrument;

    c. The efficiency of each instrument, for each type of radioactive material to be tested, including the supportive calculations documenting such efficiency; and

    d. The minimum sensitivity of each instrument, for each type of radioactive material to be tested, including the supportive calculations documenting such minimum sensitivity. At a minimum, the instrument used must be capable of detecting 185 Bq (0.005 μCi) of the radioactive material being tested. For radium-226, the instrument must be sensitive enough to detect 185 Bq (0.005 μCi) external radon-daughter contamination or the escape of radon at the rate of 37 Bq (0.001 μCi) per 24 hours.

2. Identify the calibration standards to be used in the analysis of each radioactive material to be tested. The identification should include the manufacturer, model, radionuclide and activity of each standard. Such standards should be traceable to a national standard.

3. Describe the calibration procedures and the frequency of calibration for each instrument.

4. Describe the material or leak test kit to be used in collecting the leak test samples.

5. Describe in detail the procedure for performing the analysis of the leak test samples.

6. Submit sample calculations showing the conversion of the raw counting data to units of becquerel or microcurie.

7. Describe the method for disposing of contaminated leak test samples.

8. Describe the training and experience of each person who will evaluate the leak test samples.
9. Describe the records to be maintained for each leak test. These shall include:

a. The location of the source that was tested for leakage and/or contamination;

b. The date the sample was collected;

c. The individual collecting the sample;

d. The person performing the analysis;

e. The date the analysis was performed;

f. The unique identification of the source tested (e.g., manufacturer, model, serial number, etc.);

g. The radionuclide and the activity of radioactive material contained in the source; and

h. The results of the test expressed in units of becquerel or microcurie. Actual test results shall be reported unless such results are less than 185 Bq (0.005 µCi).

Note: The record keeping requirements are specified in 32 Ill. Adm. Code 335.2050(c).

APPENDIX L

ADDITIONAL PROCEDURE FOR THE THERAPEUTIC USE OF RADIOPHARMACEUTICALS

In addition to those procedures required by the regulations and those identified as general safety precautions, the following additional procedure will be followed when handling therapeutic radiopharmaceuticals or when handling hospitalized patients treated with therapeutic radiopharmaceuticals:

A. No person will be allowed to help prepare or administer a dosage of iodine-131 without having a baseline bioassay record on file.

B. All therapy doses of I-131 will be opened in an operating fume hood.

C. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amount of contamination to be expected. Attention will be given to objects likely to be touched by the patient (e.g., telephones, door knobs and other items that would be difficult to decontaminate).

D. Attending personnel will wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins or other items contacting material from the patient's body.

E. Disposable items should be used in the care of these patients, whenever possible.

F. If a nurse, who is a declared pregnant worker, an attendant or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer (RSO) or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and lukewarm water.

G. The form, "Nursing Instructions for Patients Treated with Phosphorous-32, Gold-198 or Iodine-131" (or a similar form containing all the requested information) will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

H. Nurses shall read and follow the posted restrictions before caring for a therapy patient. The Nuclear Medicine Department staff, medical physics staff or the RSO will answer any questions about the care of therapy patients. Nursing personnel who attend the patient will wear personnel monitoring devices.

I. No nurse, who is a declared pregnant worker, visitor or attendant who is pregnant will be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard or unless otherwise noted on the precaution sheet on the patient's chart. Female visitors will be asked whether they are pregnant.

J. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 meter) from the patient.

K. Patients containing radioactive material are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department staff, medical physics staff or the RSO.

L. If urine and vomitus from I-131 therapy patients are collected for medical analysis, they will be stored for decay in the radioactive waste storage area. Such stored waste will be retained until it has reached background levels, as measured with a low-level monitoring instrument. It will then be released to the sanitary sewer system.

M. If a therapy patient should need emergency surgery or should die, notify the RSO or the Nuclear Medicine Department staff immediately.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____ Room No.: _____

Physician's Name: _____ Radionuclide Administered: _____

Time/Date of Source Administration: _____ a.m./p.m. Dosage Administered: _____

Method of Administration: _____ Signature: _____ Date: _____

RADIATION EXPOSURE RATES

Survey Instrument Used: Make - _____; Model - _____; Serial Number - _____

Unrestricted areas: Door - _____mR/hr; Room - _____mR/hr; Adj. Room - _____mR/hr

Patient supine in bed or _____

Date	Time	Bedside	3 ft (1 m) from Bed	Door	_____
_____	_____ a.m./p.m.	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
_____	_____ a.m./p.m.	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
_____	_____ a.m./p.m.	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
_____	_____ a.m./p.m.	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
_____	_____ a.m./p.m.	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr

INSTRUCTIONS

Visitor Restrictions:

- ☐ No visitors.
- ☐ No visitors under 18 or pregnant.
- ☐ _____ minutes each day maximum for each visitor.
- ☐ Visitors must stay behind line on floor at all times.

Nursing Restrictions:

- ☐ Patient is restricted to room.
- ☐ No nurse, who is a declared pregnant worker, may render care.
- ☐ ____ minutes each day per nurse in the room.

Patient Care:

- ☐ Wear disposable gloves. Wash hands after caring for patient.
- ☐ Discard linen, bedclothes, plates, utensils, dressings, etc., in boxes in room.
- ☐ Collect urine in containers provided. Discard feces in toilet.
- ☐ Discard urine and feces in toilet. Flush three times.
- ☐ Housekeeping personnel are not permitted in the room.
- ☐ Only RSO may release room to admitting office.
- ☐ Wear your radiation monitor when caring for patient. Leave monitor at nursing station at the end of your shift. You must use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ☐ _____

In case of emergency, or if you have a question, call:

RSO: _____ Work: _____ Home: _____ Pager: _____

MD: _____ Work: _____ Home: _____ Pager: _____

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APPENDIX M

RADIOIODINE BIOASSAY PROCEDURE

CALIBRATION

This bioassay procedure uses a sodium iodide crystal and single channel analyzer (such as an uptake probe) to determine thyroid burden. Calibration of the system will be performed annually.

A. Set Window or Region of Interest

The window or region of interest must be set to detect emissions for the radionuclide you are trying to detect. In the case of I-131, the region of interest must be in the area of 364 keV.

Using the minimum detectable activity calculations described in Appendix C, demonstrate that the system you are using can detect 1.48 kBq (0.04 μCi) of I-131. (Submit these calculations with Exhibit C.)

B. Establish Background

Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a 1 minute count. Record results.

C. Count Standard

A known (measured) amount of radioactivity must be used as the standard. When assaying for I-131, an I-131 standard (or a standard source of known activity that emits photons of approximately the same energy as I-131, e.g., Ba-133) must be used. I-131 liquid or capsule may be used and must be measured and corrected for decay. Place the standard in a thyroid phantom*. Hold probe against the phantom in an established geometry, similar to the geometry to be used when performing a bioassay on an individual, for required amount of time (1 min.). Record results.

*Note: Specifications for design of a neck phantom can be found in American National Standard ANSI N44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom."

D. Establish System Efficiency

Standard CPM - Background CPM = Net Standard CPM

$$\frac{\text{Net Standard CPM}}{\text{Standard Activity}(\mu Ci)} \times \frac{100}{2.2 \times 10^6 \text{ DPM}/\mu Ci} = \% \text{ Efficiency}$$

INVESTIGATION LIMITS

E. Establish In-House Investigation Limits

1. The Radiation Safety Officer (RSO) shall be notified whenever the thyroid burden at the time of measurement exceeds 37 kBq (1.0 μCi) of I-131. The RSO shall perform an investigation into the cause of the exposure and the potential for further exposure and develop corrective actions to prevent recurrence.

2. The RSO shall be notified immediately whenever the thyroid burden at the time of measurement exceeds 185 kBq (5.0 μCi) of I-131. The RSO must perform an investigation, as described above, and must perform weekly bioassay on the individual until the individual's thyroid burden is less than 37 kBq (1.0 μCi) of I-131.

Note: In-house investigation limits are adopted from U. S. Nuclear Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program."

MEASUREMENT

F. Measure Thyroid Gland

1. Perform measurements in a low-background area.

2. Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a 1 minute count. Record results.

3. Hold probe in the center of neck near Adam's apple for required amount of time (1 min). Record results.

4. Subtract background from thyroid gland count to obtain net counts. Record results.

5. Calculate and record the amount of radioactivity in thyroid by using the equation below:

   A. $$\frac{\text{Net counts (CPM)} \times 100}{\% \text{ Efficiency} \times 2.2 \times 10^6 \text{ dpm}/\mu Ci} = X\ \mu Ci$$

   B. The intake retention fraction (t = 24 hours) for I-131 is 0.133.

$$\frac{X\ \mu Ci}{0.133} = X(i)\ \mu Ci \text{ (estimate of intake)}$$

C. The inhalation ALI for I-131 is 50 μCi

$$\frac{X(i)}{50\ \mu Ci} = \%\ \text{of CEDE}$$

6. If results are less than the investigation limits established in E.1. above, you are finished with this procedure.

7. If results are more than the investigation limits established in E.1. above, notify the RSO immediately. The RSO may restrict the employee's further handling of I-131 until the thyroid burden is measured to be below the reporting limits established in E above.

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APPENDIX N

ADDITIONAL PROCEDURE FOR THE THERAPEUTIC USE OF BRACHYTHERAPY SOURCES

In addition to those procedures required by the regulations and those identified as general safety precautions, the following additional procedure will be followed when handling brachytherapy sources and patients treated with brachytherapy sources:

A. Never touch needles, capsules or unshielded containers holding brachytherapy sources. If needles, containers or capsules become loose or fall out or are removed by the patient, do not try to replace them. Use long forceps and put them in the shielded container provided or in a corner of the room. Immediately contact the Radiation Therapy Department, the Radiation Safety Officer (RSO) or the physician in charge.

B. Immediately after the sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" (or a similar form containing all the requested information) will be completed and placed on the patient's chart.

C. Special restrictions shall be noted on the precaution sheet on the patient's chart. Nurses shall read and follow these instructions before caring for a therapy patient. The Radiation Therapy Department staff, medical physics staff or the RSO will answer any questions about the care of therapy patients. Nursing personnel who attend the patient will wear personnel monitoring devices.

D. No nurse, who is a declared pregnant worker, visitor or attendant who is pregnant will be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard or unless otherwise noted on the precaution sheet on the patient's chart. Female visitors will be asked whether they are pregnant.

E. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 meter) from the patient.

F. Patients containing radioactive material are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department staff, medical physics staff or the RSO.

G. All items that may have been in contact with the patient must be checked with a radiation monitoring instrument before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.

H. If a therapy patient should need emergency surgery or should die, immediately notify the RSO, the Nuclear Medicine Agency staff or the medical physics staff.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name:_____ Room No.:_____

Physician's Name: _____ Radionuclide Administered:_____

Time & Date of Source Administration:_____ a.m./p.m. Number of Sources:_____

Total Activity: _____ Sources Will Be Removed at Approximately: _____a.m./p.m. _____

Signature: _____

RADIATION EXPOSURE RATES

Survey Instrument Used: Make - _____; Model - _____; Serial Number - _____

Unrestricted areas: Door - _____mR/hr; Room - _____mR/hr; Adj. Room - _____mR/hr

Patient supine in bed or _____

Date	Time	Bedside	3 ft (1 m) from Bed	Door	_____
_____	_____ a.m./p.m.	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr

Release certification: Patient may not be released from the hospital until the following certification is signed and dated by the Radiation Safety Officer (RSO) or the attending physician:

I have removed and counted _____ individual sources from this patient. A low-range instrument (e.g., G-M) survey of the patient indicated no remaining sources in the patient.

Signature: _____ Date: _____

INSTRUCTIONS

Visitor Restrictions:

- ☐ No visitors.
- ☐ No visitors under 18 or pregnant.
- ☐ _____ minutes each day maximum for each visitor.
- ☐ Visitors must stay behind line on floor at all times.

Nursing Restrictions:

- ☐ Patient is restricted to room.
- ☐ Patient is restricted to bed.
- ☐ Patient must not move.
- ☐ No nurse, who is a declared pregnant worker, may render care.
- ☐ ____ minutes each day per nurse in the room.

Patient Care:

- ☐ Wear your radiation monitor when caring for patient. Leave monitor at nursing station at the end of your shift. You must use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ☐ If a source appears dislodged, call the attending physician and the RSO immediately.
- ☐ Omit bed bath.
- ☐ No perineal care. Pad may be changed as necessary.
- ☐ Save surgical dressings for disposal by attending physician or RSO.
- ☐ See special oral hygiene care instructions.

In case of emergency, or if you have a question, call:

RSO: _____ Work: _____ Home: _____ Pager: _____

MD: _____ Work: _____ Home: _____ Pager: _____

APPENDIX O

SAMPLE CALCULATIONS FOR RADIOACTIVE GAS/VOLATILE MATERIAL
(e.g., Xe-133/I-131)

The following information must be submitted in support of requests to use radioactive gas/volatile material:

1. CALCULATIONS OF MINIMUM VENTILATION RATES FOR RESTRICTED AREAS REQUIRED BY PART 340

   a. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, etc.) or based on activity, distance and duration of handling. If necessary, modify the dose to account for an anticipated increase or decrease in potential exposure.

   b. Modify the DAC value to allow for the estimated annual external dose.

      A simplified method is to subtract the estimated external dose from the occupational dose limit of 50 mSv (5 rems) and divide this number by 50 mSv (5 rems). This yields the fraction of the dose limit of 50 mSv (5 rems) that would still be permitted from internal sources. Multiplying this fraction times the DAC value yields a modified DAC. These DAC values are provided in Appendix B to 10 CFR 20.

   Example:

   A new room is being designed where Xe-133 will be used. If the annual external dose is 2 rems, the modified DAC value should be based on 3 rems that could still be incurred from internal exposure. The listed DAC value for Xe-133 is 1E-4 μCi/ml.

$$DAC(modified) = \frac{3\ rems}{5\ rems}\ x\ 1E-4\ \mu Ci/ml$$

$$= 6E-5\ \mu Ci/ml$$

   If the facility in question plans to use 5.2×10^6 μCi of Xe-133 per year, what ventilation rate is required to ensure compliance with 32 Ill. Adm. Code 340.210?

Maximum Activity:

$A_0 = 5.2 \times 10^6$ μCi/year

Assume a loss rate (f) of 20%

$A = A_0 \times f$

$A = (5.2 \times 10^6$ μCi/year) X 0.2

$A = 1 \times 10^6$ μCi/year

Required Ventilation Rate:

$V = \frac{A}{C}$ where C = DAC = 6×10^{-5} μCi/ml

$$V = \frac{1 \times 10^6 \text{ μCi/year}}{6 \times 10^{-5} \text{ μCi/ml}}$$

$V = 1.7 \times 10^{10}$ ml/yr

$$V = \frac{1.7 \times 10^{10} \text{ ml}}{\text{year}} \times \frac{1 \text{ year}}{52 \text{ weeks}} \quad \frac{1 \text{ week}}{40 \text{ hours}} \times \frac{1 \text{ hour}}{60 \text{ minutes}} \times \frac{1 \text{ ft}^3}{2.832 \times 10^4 \text{ ml}}$$

$V = 4.8$ ft^3/min

The answer shows that, in order to meet the requirements of 32 Ill. Adm. Code 340.210, the nuclear medicine laboratory (RESTRICTED AREA) must have a ventilation rate of at least 5.0 ft^3/min with no recirculation of air. Where practicable, the ventilation rate should be greater than that shown necessary by the calculations. Consider every alternative in order to maintain the air concentration of Xe-133 as low as is reasonably achievable.

If the ventilation rate is inadequate to meet the requirements of 32 Ill. Adm. Code 340.210, methods of increasing ventilation or reducing the activity must be implemented.

2. AIR CONCENTRATIONS OF RADIOACTIVE GAS/VOLATILE MATERIAL IN UNRESTRICTED AREAS

Licensees who make releases of radioactive gas/volatile material to unrestricted areas during use, storage and disposal are required to perform monitoring (measurements or calculations) to ensure that they are in compliance with 32 Ill. Adm. Code 340.210. Many facilities do not have sufficient air flow to achieve the necessary dilution to unrestricted areas. The following procedure may be used to estimate the concentrations of radioactive gases in effluent to unrestricted areas:

a. Estimate the maximum amount of radioactive gas/volatile material to be released per year (A). This should include all anticipated losses during use, storage and disposal.

b. Determine the flow rate of the exhaust system and calculate the air flow per year (V).

c. For unrestricted areas, 32 Ill. Adm. Code 340.1030 requires that the air concentration (C):

$C = \frac{A}{V} \leq$ Maximum concentration as listed in Table II, Column I of 10 CFR 20 Appendix A.

d. Sample Problem:

A nuclear medicine laboratory plans to use 5.2×10^6 μCi of Xe-133 per year (10 mCi per patient and 10 studies per week). A fume hood is available for the release of Xe-133 and has a measured airflow of 168 ft/min. with an opening of 8 ft^2. What is the average concentration of Xe-133 at the point of release from the fume hood exhaust (assuming all Xe-133 from collection bags, filters, etc. has been released)?

Volume:

(1 ft^3/min = 1.7×10^6 ml/hr = 6.8×10^7 ml/40-hr wk = 1.5×10^{10} ml/yr)

$$V = 168 \frac{ft}{min} \times 8\ ft^2$$

$$V = 1344 \frac{ft^3}{Min} \times 1.5 \times 10^{10} \frac{ml/yr}{ft^3/min}$$

$$V = 2.02 \times 10^{13}\ ml/yr$$

Concentration:

$$C = \frac{5.2 \times 10^{6}\ \mu Ci/year}{2.02 \times 10^{13}\ ml/yr}$$

$$C = 2.6 \times 10^{-7}\ \mu Ci/ml$$

The concentration of radioactive gas vented to the atmosphere is less than the maximum concentration of 7×10^{-7} μCi/ml listed in Table II, Column I of 10 CFR 20 Appendix A.

APPENDIX P

DIRECT READING DOSIMETER USE AND CALIBRATION

USE OF DIRECT READING DOSIMETERS

A. Each direct reading dosimeter (dosimeter) used must have been calibrated within one year prior to its use.

B. Only one person shall be assigned a particular dosimeter at any one time.

C. A log must be made to document the measured exposures of each individual using a dosimeter. This log shall record the date and time of each entry and the name and unique identification number used for dose records (e.g., social security number) of the monitored individual.

D. At the beginning of each shift or prior to entering an area where dosimeters are needed, the dosimeter must be zeroed (charged) to indicate essentially no exposure. If this is not practicable, document the initial exposure reading in the dosimeter log.

E. Enter the exposure reading from the dosimeter in the dosimeter log daily (immediately before the end of a shift or after all entries into a restricted area have been performed).

F. The Radiation Safety Officer (RSO) must be notified immediately if a dosimeter is discharged beyond its range.

G. At least once each month, total the exposures in the log for each individual who used a dosimeter during that period. These totals may be kept in the log or with other dosimetry results maintained by the licensee.

A. The calibration of a direct reading dosimeter (dosimeter) shall be performed in accordance with the following:

1. The radionuclide sources used for calibration shall be approximate point sources.

2. The source activities shall be traceable within 5% accuracy to the NIST (previously the NBS).

3. The dosimeter shall be calibrated at two scale readings, separated by at least 50 percent of the full-scale reading.

4. The exposure measured by the dosimeter shall not differ from the calculated (true) exposure by more than $\pm$ 20 percent of the calculated (true) value.

5. Dosimeters shall be charged, placed in a radiation-free environment (excluding background radiation), then read after a minimum of 24 hours has passed. A dosimeter shall be considered defective if the rate of leakage is greater than 5 percent of the dosimeter full-scale reading.

B. Records of calibration shall include:

1. Radionuclide used,

2. Activity and activity assay date of source,

3. Date of dosimeter calibration,

4. Activity of source at date of dosimeter calibration,

5. Calculated (true) and measured radiation values,

6. Respective distance from source for each calculated and measured radiation value,

7. Elapsed time of exposure for each measured radiation value,

8. Necessary scale correction factors (required if calculated and measured radiation values do not agree within $\pm$ 20 percent),

9. Make, model and serial number of dosimeter calibrated and

10. Signature of individual who performed the calibration.

APPENDIX Q

SUBJECTS TO BE COVERED DURING RADIATION SAFETY TRAINING

The following training program will be adopted and provided to individuals who frequent areas where radioactive material is used or stored in order to avoid radiological health protection problems. Training will be in lecture format with a written outline of the presented scope provided to the individuals. Supporting handouts, audio/video tape may also be utilized. Training is provided initially before assigning duties involving radioactive material and following changes in duties or procedures or potential radiation hazards. Refresher training which covers all of the below topics is provided at intervals not to exceed 12 months.

I. Fundamentals of Radiation Safety

A. Characteristics of radiation

B. Units of radiation dose and quantity of activity

C. Conversions and calculations, which are basic to the use and measurement of activity.

D. Significance of radiation dose
   1. Biological effects
   2. Radiation protection standards
      a) Occupational
      b) Public
      c) Embryo/Fetus
   3. The ALARA philosophy

E. Sources of Radiation
   1. Unsealed (internal hazard)
   2. Sealed (external hazard)

F. Methods of controlling radiation dose
   1. Working time
   2. Working distance
   3. Shielding
   4. Contamination control

G. Locations of Use
    1. Nuclear Medicine
    2. Oncology
    3. Waste Storage
    4. Shipping/Receiving
    5. Laboratories (i.e., Stress Rooms, Pathology, etc.)
    6. Other (i.e., patient rooms, etc.)

II. Radiation Detection/Measurement Instrumentation to be Used

A. Radiation monitoring instruments
    1. Operation
    2. Calibration
    3. Limitations

B. Use of personnel monitoring equipment
    1. Film badges
    2. Thermoluminescent dosimeters (TLD's)
    3. Pocket dosimeters

III. Safety Equipment to be Used

A. Remote handling equipment

B. Fume hoods

C. Storage containers

D. Personnel protective equipment (i.e., gloves, lab coats)

E. Shielding

F. Traps and collectors

IV. Control of Radioactive Material, Signs and Labels

A. Areas of use and restricted access
    1. Locks and security
    2. Supervision and control

B. Survey techniques and occasions for conducting surveys
    1. Area monitoring
    2. Contamination monitoring

C. Sign recognition and relative hazard
    1. Caution-Radioactive Material
    2. Caution-Radiation Area
    3. Caution-High Radiation Area

D. Labeling of containers, vials, syringes etc.

IV. Requirements of Pertinent State Regulations (see Section I.D. and Item 12 of this instructional set)

A. Obligation of individual to report unsafe conditions

B. Right of individual to be informed of exposures

C. Access to regulations and radioactive material license

V. Terms and Conditions of the Radioactive Material License, Active Amendments and Any Correspondence Submitted in Support of the License Application

VI. The Licensee's Written Operating and Emergency Procedures

VII. Manufacturer's Instruction Manuals for Sources/Devices

Training is provided by the Radiation Safety Officer or his designee provided the designee has participated in the training previously and has equivalent training and experience as the Radiation Safety Officer in the items to be discussed. Individuals included in the training are: nuclear medicine technologists and technicians, therapy technologists and technicians, nurses, aides, lab technicians, shipping and receiving personnel, housekeeping and maintenance personnel, security and administrative personnel and animal caretakers as appropriate.

Records of training will include the following: date of instruction, name of instructor, scope of instruction provided and signature of each participant that indicates that he/she has received and understood the information presented in the training program that is applicable to his/her duties.

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ILLINOIS EMERGENCY MANAGEMENT AGENCY
1035 OUTER PARK DRIVE
SPRINGFIELD, ILLINOIS 62704

APPLICATION FORM FOR A MEDICAL RADIOACTIVE MATERIAL LICENSE

Complete all items if this is an initial application for renewal of a license. Use supplementary sheets where necessary. Retain one copy and submit the original and one copy of the entire application to the Illinois Emergency Management Agency.

This state agency is requesting disclosure of information that is necessary to accomplish the statutory purpose as outlined under 32 Ill. Adm. Code 330. Disclosure of this information is required. Failure to provide any information may result in denial of a radioactive material license. This form has been approved by the State Forms Management Center.

ITEM 1. Type of application (Check one)
☐ NEW LICENSE ☐ RENEWAL ☐ AMENDMENT Radioactive Material License #_____

ITEM 2. Applicant's Name and Mailing Address (Applicant must be the legal entity or individual responsible for the license.)	**ITEM 3. Person to Contact Regarding This Application:**
Phone #:	Phone #:
Fax #:	Fax #:
E-mail:	E-mail:

ITEM 4. Address(es) Where Radioactive Material Will Be Used ☐ **Stored** ☐ **Used and Stored** ☐

Phone #:	Phone #:

Request for TEMPORARY JOB SITES (≤ 180 days during any consecutive twelve-month period): Yes ☐ No ☐

ITEM 5a. Individual(s) Who Will Use Radioactive Material (Attach evidence of appropriate Training and Experience).
List names and requested uses of material.

Name: _____ Subparts: _____

Name: _____ Subparts: _____

Name: _____ Subparts: _____

Name: _____ Subparts: _____

Name: _____ Subparts: _____

Name: _____ Subparts: _____

Name: _____ Subparts: _____

ITEM 5.b. Teletherapy Physicist ☐ Not Applicable

Name: _____
(Attach Exhibit B for evidence of Training & Experience.)

ITEM 6. Radiation Safety Officer (RSO) (Attach Exhibit B for evidence of Training and Experience)

Name: _____ Phone #: _____

☐ No duties and responsibilities other than those described in 32 Ill. Adm. Code 335.1020(b).

☐ Duties and responsibilities in addition to those specified in 32 Ill Adm. Code 335.1020(b) are attached.

ITEM 7a. Radioactive Material (Check all that apply)

RADIONUCLIDE	CHEMICAL and/or PHYSICAL FORM	MAXIMUM ACTIVITY PER SOURCE	MAXIMUM POSSESSION LIMIT
☐ Co-60	Sealed Source for use in a teletherapy unit as identified in 32 Ill. Adm. Code 335.8010 (Subpart I) _____ (Identify Manufacturer & Models, etc.)	_____	_____
☐ Any in 32 Ill. Adm.Code 335.3010	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.3010 (Subpart D).		As needed
☐ Any in 32 Ill. Adm. Code 335.4010 **OR**	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.4010 (Subpart E), **excluding gases**.		
☐ Any in 32 Ill. Adm. Code 335.4010	Any radiopharmaceutical **as aerosols or gases** identified in 32 Ill. Adm. Code 335.4010 (Subpart E).		As needed
☐ Any in 32 Ill. Adm. Code 335.5010 **OR**	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.5010 (Subpart F).		As needed
☐ Any in 32 Ill. Adm. Code 335.5010	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.5010 (Subpart F) **that does not require hospitalization.**		As needed
☐ Any in 32 Ill. Adm. Code 335.6010	Any radiopharmaceutical identified in 32 Ill. Adm. Code 335.6010 (Subpart G).		As needed
☐ Any in 32 Ill. Adm. Code 335.7010	Any sealed source identified in 32 Ill. Adm. Code 335.7010 (Subpart H), **excluding remote afterloader devices.**		As needed
☐ Any in 32 Ill. Adm. Code 335.7010	Any sealed source **in remote afterloader devices identified** in 32 Ill. Adm. Code 335.7010 (Subpart H). _____ (Identify Manufacturer & Model, etc.)		As needed

32 Ill. Adm. Code 335.2040 will be authorized unless otherwise indicated.

ITEM 7b. Radioactive Material for Uses Not Listed in Item 7.a. (Check all that apply)

RADIONUCLIDE	CHEMICAL and/or PHYSICAL FORM and MATERIAL USE	MAXIMUM ACTIVITY PER SOURCE	MAXIMUM POSSESSION LIMIT
☐ Any in 32 Ill. Adm. Code 330.220(f)(1)	Prepackaged kits.		
☐			
☐			

ITEM 8. Radiation Safety Committee (Check one)

☐ No duties and responsibilities other than those described in 32 Ill. Adm. Code 335.1030(b).

☐ Duties and responsibilities in addition to those described in 32 Ill. Adm. Code 335.1030(b) are attached.

ITEM 9. Instrumentation

Attach a completed Exhibit C from Instructional Set 52.2 or equivalent.

☐ In accordance with 32 Ill. Adm. Code 310.30, we hereby request an exception from the requirements of 32 Ill. Adm. Code 335.2020 for possessing a radiation survey instrument over the range of 1 mrem - 1000 mrem per hour, since we are only using diagnostic radiopharmaceuticals and we do not use a Mo-99/Tc-99m generator.

ITEM 10a. Dose Calibrator Calibration and Operability Checks (Check one)

☐ We will calibrate dose calibrators in accordance with the procedure identified in Appendix D of Instructional Set 52.2 dated November 1995.

☐ We will calibrate dose calibrators in accordance with the attached procedures.

ITEM 10b. Instrument Calibration and Operability Checks (Check one)

☐ Radiation survey/monitoring instruments will be calibrated by a service company authorized to perform such services. We will maintain a copy of the company's license authorizing such services.

☐ We will calibrate radiation survey/monitoring instruments in accordance with the attached procedures, which contain all information requested in Appendix E of Instructional Set 52.2 dated November 1995.

ITEM 11. Facilities and Equipment

☐ Diagrams of radioactive material use and storage areas are attached.

ITEM 12. Personnel Training Program (Check one)

☐

☐ Description of training program, including frequency, form and duration of training is attached.

ITEM 13. Procedure for Ordering and Receiving Radioactive Material

☐ Procedure for ordering and receiving radioactive material is attached.

ITEM 14. Procedure for Safely Opening Radioactive Material Packages (Check one)

☐ We will use the procedure identified in Appendix H of Instructional Set 52.2 dated November 1995.

☐ Procedure is attached.

ITEM 15. General Rules for the Safe Use of Radioactive Material (Check one)

☐ We will use the procedure identified in Appendix I of Instructional Set 52.2 dated November 1995.

☐ Procedure is attached.

ITEM 16. Emergency Procedure (Check one)

☐ We will use the procedure identified in Appendix J of Instructional Set 52.2 dated November 1995.

☐ Procedure is attached.

ITEM 17. Waste Disposal (Check one)

☐ We do not wish authorization for alternate disposal methods.

☐ Alternate disposal methods are detailed in an Attachment to this application. (This includes Decay-in-Storage procedures for isotopes with T 1/2 < 90 days.)

ITEM 18. Testing Sealed Sources for Leakage and/or Contamination (Check one)

☐ We will use a commercial service to perform analysis of leakage and/or contamination samples. We will maintain a copy of the commercial service's license authorizing such services.

☐ We will perform our own sample analysis for source leakage and/or contamination. Procedure is attached.

ITEM 19. Therapeutic Use of Radiopharmaceuticals (Check one)

☐ Not applicable.

☐ We will use the procedure identified in Appendix L of Instructional Set 52.2 dated November 1995.

☐ Procedure is attached.

ITEM 20. Bioassays for Therapeutic Use of Radioiodine (Check one)

☐ Not applicable.

☐ We will use the procedure identified in Appendix M of Instructional Set 52.2 dated November 1995.

☐ Procedure is attached.

ITEM 21. Sealed Sources for Brachytherapy (Check one)

☐ Not applicable.

☐ We will use the procedure identified in Appendix N of Instructional Set 52.2 dated November 1995.

☐ Procedure is attached.

ITEM 22. Procedure for Use of Radioactive Gases (Check one)

☐ Not applicable.

☐ Unrestricted area concentration and required ventilation rate calculations are attached.

ITEM 23. Personnel Monitoring (Check all that apply)

TYPE	EXCHANGE FREQUENCY		FILM	TLD	OSL
☐ Whole body	☐ Monthly	☐ Quarterly	☐	☐	☐
☐ Extremity	☐ Monthly	☐ Quarterly	☐	☐	☐

☐ Direct reading dosimeters will be used and calibrated in accordance with Appendix P of Instructional Set 52.2 dated November 1995.

☐ Direct reading dosimeter use and calibration procedures are attached.

ITEM 24. License Fees (Refer to 32 Ill. Adm. Code 331)

Please do not submit your fee payment. New applicants will be billed a prorated fee for the portion of the billing year remaining from the date the application is received. Licensees adding sites or changing fee categories will be billed when the license is amended. Existing licensees and applicants are also subject to annual bills as specified in 32 Ill. Adm. Code 331.

Fee Category_____

ITEM 25. Financial Assurance

The applicant must satisfy applicable financial assurance requirements as described in 32 Ill. Adm. Code 326.

NEW APPLICANT (Check one)

☐ Exempt ☐ $25,000 arrangement will be provided at a later date ☐ Reclamation plan/cost estimate attached

RENEWAL OR AMENDMENT (Check one)

☐ Exempt ☐ Existing document reviewed – no changes necessary ☐ Limiting condition applies
☐ Updated reclamation plan/cost estimate attached

ITEM 26. Certification

EACH APPLICANT MUST COMPLETE SECTION A.

A. I have reviewed the above items and hereby certify that my radiation protection program meets the current 32 Ill. Adm. Code, radioactive materials license with active amendments, operating procedures and ALARA Program, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE:_____ DATE:_____

NAME:_____ TITLE:_____
(Print or Type)

COMPLETE THIS SECTION IF THE APPLICANT IS AN INDIVIDUAL:

B. If you are applying as an individual, rather than as a corporation or other legal entity, you must provide the following information in order to process your application:

Have you defaulted on an educational loan guaranteed by the Illinois Student Assistance Commission? Yes ☐ No ☐

I certify, under penalty of perjury, that I am not more than 30 days delinquent in complying with a child support order. Failure to certify may result in a denial of the license and making a false statement may subject you to contempt of court. (5 ILCS 100/10-65)

I declare that all information either included with or appearing on this application is accurate and true to the best of my knowledge.

SIGNATURE:_____ DATE:_____

APPLICANT'S SOCIAL SECURITY NUMBER:_____

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EXHIBIT B

FORM IEMA.FLM-001M SUPPLEMENT A

Documentation of Training and Experience Required by 32 Ill. Adm. Code 335, Subpart J

SUPERVISED INDIVIDUAL:	RADIOACTIVE MATERIAL LICENSE NO.:
INDICATE DESIRED AUTHORIZATION(S) BY CHECKING ALL THAT APPLY:	32 ILL. ADM. CODE TRAINING REFERENCES
☐ Radiation Safety Officer (RSO)	§335.9010,9020
☐ Uptake, Dilution or Excretion Studies	§335.9030
☐ Imaging and Localization Studies	§335.9040
☐ Radiopharmaceutical Therapy	§335.9050 - 335.9090
☐ Sr-89/P-32 only	§335.9080
☐ Use of Sealed Sources for Diagnosis	§335.9130
☐ Brachytherapy	§335.9100
☐ Ophthalmolic Use of Sr-90	§335.9120
☐ Teletherapy	§335.9140
☐ Teletherapy Physicist	§335.9150

If the individual is named as an authorized user, RSO or Teletherapy Physicist on an existing ILLINOIS Radioactive Material License, then specify the number of that ILLINOIS License. If the individual is named as an authorized user, RSO or Teletherapy Physicist on a NON-ILLINOIS Radioactive Material License, then submit a copy of that license. Use the other parts of this form if the individual is not approved for all desired authorizations on the referenced (or attached) license.

Physician, RSO, or Teletherapist Physicist is an authorized user on

Illinois Radioactive Material License No. _____

OR

A copy of License No: _____ issued by _____ is attached.

********** **OR** **********

Specify board certification(s). Evidence (i.e., photocopy) of each certification MUST be submitted with this form. If the individual is not fully certified OR if the certification does not satisfy Subpart J requirements, then other parts of this form MUST be used.

Board _____ Specialty _____ Year _____

Board _____ Specialty _____ Year _____

********** **OR** **********

I hereby certify that, under my supervision, _____ has met the training requirements specified in 32 Ill. Adm. Code 335. _____ for the use(s) of radioactive material specified above. The supervised training and experience was at:

Medical Institution _____

Address & Telephone _____

Institution's Radioactive Material License No. _____

Dates of Work/Clinical Experience: From _____ To _____ Total Hours _____

Supervising Individual's Name (typed or printed) _____

Supervising Individual's Signature and Date _____

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EXHIBIT C

INSTRUMENTATION FORM

1. Portable Radiation Detection Instruments
(1 μSv/hr to 500 μSv/hr or 0.1 mrem/hr to 50 mrem/hr)

Manufacturer:_____

Model:_____

Available:_____

Range:_____

Window Thickness:_____
(mg/cm^2)

Detector Type:_____
(G-M, Ion, etc.)

2. Portable Radiation Measurement Instruments
(10 μSv/hr to 10 mSv/hr or 1 mrem/hr to 1000 mrem/hr)

Manufacturer:_____

Model:_____

Available:_____

Range:_____

Window Thickness:_____
(mg/cm^2)

Detector Type: _____
(G-M, Ion, etc.)

3. Fixed Area Monitor (For high radiation areas)

Manufacturer:_____

Model: _____

Available: _____

Range: _____

4. Liquid Scintillation Counter (If used to analyze wipes*)

   Manufacturer:_____

   Model: _____

   *Minimum Detectable Activity: _____

5. Well Counter (If used to analyze wipes*)

   Manufacturer:_____

   Model: _____

   *Minimum Detectable Activity: _____

6. Instrument Used for Analysis of Leak Tests

   (Generic Description)_____

   Manufacturer:_____

   Model: _____

   *Minimum Detectable Activity: _____

7. Thyroid Bioassay Probe

   Manufacturer:_____

   Model: _____

   Range/*Minimum Detectable Activity:_____

8. Other Instruments (Continue on separate sheet if necessary.)

   (Generic Description)_____

   Manufacturer:_____

   Model: _____

   Range: _____

   * Submit calculations as described in Appendix C.

EXHIBIT D

Illinois Emergency Management Agency

Division of Nuclear Safety
1035 Outer Park Drive
Springfield, Illinois 62704

This State agency is requesting disclosure of information that is necessary to accomplish the statutory purpose as outlined under 420 ILCS 40/1-40/44. Disclosure of this information is required. Failure to provide any information will result in this form not being processed. This form has been approved by the Forms Management Center.

CERTIFICATE
TERMINATION AND DISPOSITION OF RADIOACTIVE MATERIAL

LICENSEE:	**LICENSE NUMBER:**
ADDRESS:	
	TELEPHONE NUMBER:

The following information is provided in accordance with 32 Ill. Adm. Code 330.320, "Expiration and Termination of Licenses."
This regulation appears on the back of this form. Check all that apply below.

☐ 1. All use of radioactive material authorized under the above referenced license has been terminated.

☐ 2. Radioactive contamination has been removed to the level outlined in 32 Ill. Adm. Code 340.Appendix A, to the extent practicable.

☐ 3. All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows:

☐ Transferred to (Name and Address): _____

_____

_____

_____

who is authorized to possess such material under License Number _____

issued by (Licensing Agency): _____

☐ Decayed, surveyed and disposed of as non-radioactive waste.

☐ Licensed under License Number: _____

issued by (Licensing Agency): _____

☐ No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.

☐ Other (Attach additional pages).

☐ 4. Attached are radiation surveys or the equivalent as specified in 32 Ill. Adm. Code 330.320(d)(1)(E).

☐ 5. Records required to be maintained for the license requested to be terminated are available at the following location:

Name: _____

Address: _____

_____

_____

Telephone No.: _____ Contact Person: _____

☐ 6. Additional remarks. (Attach additional pages.)

THE UNDERSIGNED, ON BEHALF OF THE LICENSEE, HEREBY CERTIFIES THAT LICENSABLE QUANTITIES OF RADIOACTIVE MATERIAL UNDER THE JURISDICTION OF THE ILLINOIS EMERGENCY MANAGEMENT AGENCY ARE NOT POSSESSED BY THE LICENSEE. IT IS THEREFORE REQUESTED THAT THE ABOVE REFERENCED LICENSE BE TERMINATED.

SIGNATURE: _____ DATE: _____

NAME: _____ TITLE: _____
(print or type)

IL 473-00084 (DRM KLM.007) **85** **(Rev. 2/97)**

Section 330.320 Expiration and Termination of Licenses

a) Except as provided in Section 330.330(b), the authority to engage in licensed activities as specified in the specific license shall expire at the end of the specified day in the month and year stated therein. Any expiration date on a specific license applies only to the authority to engage in licensed activities. Expiration of a specific license shall not relieve the licensee of responsibility for decommissioning its facility and terminating the specific license.

b) Each licensee shall notify the Agency immediately, in writing and request termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. This notification and request for termination shall include the documents required by subsection (d) below and shall otherwise substantiate that the licensee has met all of the requirements in subsection (d) below.

c) No less than 30 days before the expiration date specified in the license, the licensee shall either:

1) Submit an application for license renewal under Section 330.330; or

2) Notify the Agency, in writing, if the licensee decides not to renew the license. The licensee requesting termination of a license shall comply with the requirements of subsection (d) below.

d) Termination of Licenses

1) If a licensee does not submit an application for license renewal under Section 330.330, the licensee shall, on or before the expiration date specified in the license:

A) Terminate use of radioactive material;

B) Remove radioactive contamination to the level outlined in 32 Ill. Adm. Code 340.Appendix A, to the extent practicable;

C) Properly dispose of radioactive material;

D) Submit a completed Agency Form KLM.007; and

E) Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The radiation survey report shall specify the instrumentation used and certify that each instrument was properly calibrated and tested. The licensee shall, as applicable, report levels or quantities of:

i) Beta and gamma radiation at 1 centimeter from surfaces in units, multiples, or subunits of sieverts or rem per hour;

ii) Gamma radiation at 1 meter from surfaces in units, multiples, or subunits of sieverts or rem per hour;

iii) Removable radioactivity on surfaces in units, multiples, or subunits of becquerels or curies per 100 square centimeters of surface area, or in disintegrations (transformations) per minute per 100 square centimeters of surface area;

iv) Fixed radioactivity on surfaces in units, multiples, or subunits of becquerels or curies per 100 square centimeters of surface areas or in disintegrations (transformations) per minute per 100 square centimeters of surface area;

v) Radioactivity in contaminated liquids such as water, oils or solvents in units, multiples, or subunits of becquerels or curies per milliliter of volume; and

vii) Radioactivity in contaminated solids such as soils or concrete in units, multiples, or subunits of becquerels or curies per gram of solid.

2) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The Agency will notify the licensee, in writing, of the termination of the license.

3) If detectable levels or residual radioactive contamination attributable to activities conducted under the license are found:

A) The license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Agency notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of subsection (e) below.

B) In addition to the information submitted under subsections (1)(D) and (1)(E) above, the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

e) Each licensee who possesses residual radioactive material under subsection (d)(3) above, following the expiration date specified in the license, shall:

1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

(Source: Amended at 18 Ill. Reg. 5553, effective March 29, 1994)